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Adverse Drug Reaction Reporting of Paracetamol IV Case Report

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Abstract: *Adverse drug reactions (ADRs) are harmful effects that can occur from self-medicating, taking excessive medicine, or properly prescribed drugs. Most side effects can be prevented by careful use and adherence to doctor's prescriptions. This article focuses on paracetamol, its effects in the body, and potential side effects. It emphasizes the importance of correct dosing based on age and weight to ensure safety and efficacy. Special education for healthcare staff on precise dosing, especially regarding IV paracetamol in pediatric practice, is essential*

Keywords*:* Acetaminophen; Paracetamol; Propacetamol; Cyclooxygenase-2 inhibitors

I. INTRODUCTION

Adverse drug reactions (ADRs) are harmful effects caused by medicines and a common reason for unplanned hospital visits. A detailed medication history helps doctors avoid repeating harmful drugs. To prevent ADRs, doctors should avoid risky medicines for vulnerable patients, use safe combinations, or monitor blood tests. Reporting suspected ADRs, such as through the Yellow Card Scheme in the UK, is vital, but many cases go unreported. If unsure, it's better to report a possible ADR.[1] An adverse drug reaction (ADR) is a harmful or unexpected response to a medicine, common and burdensome on healthcare systems. The U.S. FDA's Adverse Event Reporting System (FAERS) tracks ADRs, with over 1.25 million serious cases reported in 2022, including nearly 175,000 deaths.[2]Adverse drug reactions (ADRs) can worsen health, lead to death, increase hospital visits, and raise healthcare costs. Healthcare professionals must recognize, treat, and prevent ADRs. The ICH defines ADRs as harmful, unintended responses to normal drug doses for prevention, diagnosis, or treatment. An adverse drug event (ADE) is any unexpected effect during medication use, but not necessarily caused by the drug. Edwards et al. broadened the definition, describing ADRs as harmful reactions that predict future risks and require prevention, treatment, or dosage adjustment.[3,4,5]

History of paracetamol ADR

A14-year-old male presented with painful oral and lip ulcers, eye redness, and watery discharge for 5 days, along with lesions on the chest, limbs, and genitalia. Healed target-like lesions were noted on the chest and axilla.[6] A 51-year-old female presented with a burning mouth sensation, gum swelling, and bleeding after taking Gripamol (Paracetamol) for the flu. She had no history of drug allergies. Oral exam revealed a perioral rash, cracked lips, and hand redness and swelling.[7]A 30-year-old woman developed a red rash and painful tongue sores the day after taking a paracetamol-diclofenac combination for fever. The rash started in body folds and spread to the neck, legs, and under the breasts. She had no prior similar reactions or other medications. Exam revealed symmetrical red, flat rashes in flexural areas. Diagnosed with SDRIFE, likely due to paracetamol, she was treated with oral steroids, and the rash resolved in 10 days.[8]

Classification of ADR:

In comparison, the way allergies and anaphylaxis are classified and named has changed a lot over time. There are now two main ways to classify bad reactions to drugs. The first system, which is well-known, includes:

Type A (Augmented): Reactions that depend on the drug dose and are predictable.

Type B (Bizarre): Reactions that do not depend on the dose and are unpredictable.

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These are often used for reactions in anesthesia and intensive care. Later, more types (C to F) were added to expand the classification.(Table 1)[9]

In 2003, Aronson and Ferner introduced the DoTS system to classify side effects that don't fit existing categories. It considers three factors: dose-relatedness (reaction based on drug amount), time-relatedness (timing of reaction after taking the drug), and patient susceptibility (how individual traits like age or genetics influence the reaction).[10]

Table 1. Classification of adverse drug reactions. Adapted with permission

Types of reaction	Features	Example
A – Augmented	Dose-related Common Related to known pharmacological effect Predictable	Hypotension with propofol
B – Bizarre	Non-dose-related Unpredictable Uncommon Not related to known pharmacological action of drug	Anaphylaxis Malignant hyperthermia Suxamethonium apnoea
C – Chronic	Dose-related Time-related Uncommon Related to cumulative dose	Propofol infusion syndrome
D – Delayed	Time-related Often dose-related Uncommon	Fluoride nephrotoxicit
E – End of us	Uncommon Occurs after withdrawal of drug	Rebound hypertension following cessation of clonidine infusion
F – Failure	Dose-related Uncommon May be caused by drug interactions	Failure of oral contraceptive pill with sugammadex use

Aim:

Aim of these case report observation study is a study of adverse drug reaction.it focus on the adverse drug reaction of paracetamol drug.

Objective:

Study of adverse drug reaction occurred due of paracetamol

Material and Method

Study Title:

To study adverse drug reaction due to paracetamol drug.

Study Location & Duration:

The Present study was conducted at Manipal Hospital, Baner during the period of01 Nov 2024 to 20 Nov 2024.

Study Design:

Case report observational study

Source of study population:

OPD patient visited to Manipal Hospital, Baner.

Inclusion:

Patient' s name, age, gender.

Drug Prescribed.

Dosage of Drugs Prescribed & dosage form.

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Route of Administration.

Exclusion:

Incomplete information regarding patient

Data collection:

Data on the Reported ADRs will be evaluated to understand the pattern of the ADRs with respect to patient demographic disease, Nature of the reactions, characteristics of the drugs involved, and outcome of the reactions.

Criteria for identifying ADRs:

ADR identified by physicians will be considered and will be included in the study.

Analysis of ADRs:

Nature and description of ADDRs reported.

Causality Assessment of ADR Based on Algorithm:

The degree of association of an adverse of an adverse reaction with a drug is done with the help of Naranjo's algorithm.

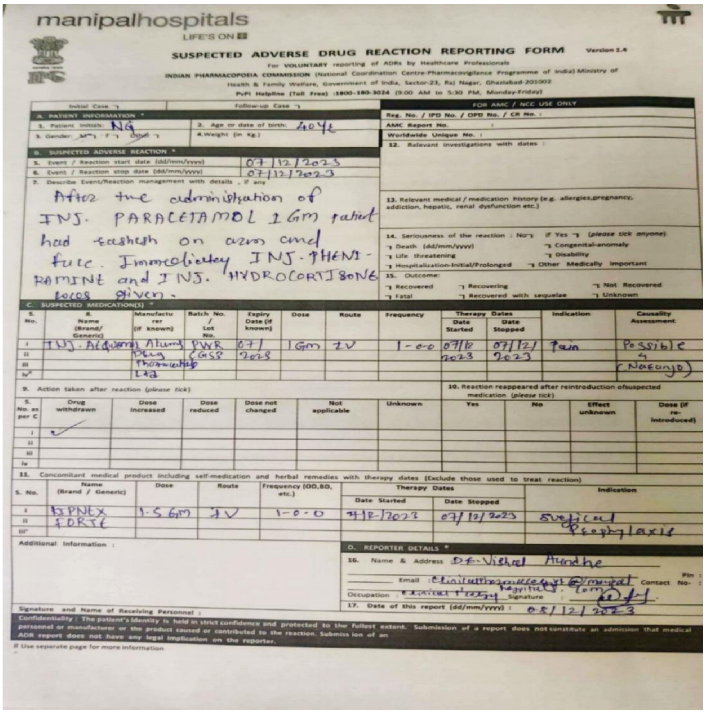
Severity Of ADR's:

After the causality assessment has been done, the severity of the ADR is analyzes using adapted Hart wig severity scale.

Patient Information:

- Patient Initials: NG
- Age:40yrs.
- Sex: Female
- Hospital/Clinic: Manipal Hospital, Baner, Pune
- Therapy Dates:
- Date Started: 07/12/2024
- Date Stopped: 07/12/2024
- Indication: Pain.

Case report:


manipalhospitals
LIFE'S ON
SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
Version 1.4
INDIAN PHARMACOPOEIA COMMISSION
PvPI Helpline (Toll Free) :1800-180-3024
A. PATIENT INFORMATION
B. SUSPECTED ADVERSE REACTION
C. SUSPECTED MEDICATION(S)
D. REPORTER DETAILS

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A. SUSPECTED ADVERSE DRUG REACTION DETAILS

Drug: aequimol inj.
Batch No.: PWR CG53
Dose: 1gm.
Route: Intravenous (IV)
Expiry Date: 07/2025
Frequency: Once

B. CONCOMITANT MEDICATION DETAILS

Drug: forte
Route: IV
BD Dose: 1.5 mg

Therapy Dates:

Date Started: 07/12/2023
Date Stopped: 07/12/2023
Indication: Surgical prophylaxis

ADVERSE DRUG REACTION:

The patient who had fever. Inj. Aequimol 1g for three times a day by intravenous route was prescribed to her. After the 2nd dose of Inj Aequimol patient got itching all over the body.

TAKEN AFTER REACTION:

Inj. Avil was administered to prevent allergic reaction.
Reaction rappeared after reintroduction of suspected medication Number

REPORTER DETAILS:

Name: Dr. Vishal Aundhe
Address: Clinical Pharmacologist, Manipal Hospitals.
Contact: 9689721151
Occupation: Clinical Pharmacologist
Date of Report: 08/12/2023

Naranjo Adverse Drug Reaction Probability Scale

Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	+1
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	+2
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	+1
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	0
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	-1
6. Did the reaction reappear when a placebo was given?	-1	+1	0	0
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	0
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	+1
			TOTAL SCORE:	4

Modified from: Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-245.

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SUSPECTED DRUG AND ITS PHARMACOLOGY

Class of Drug: Analgesic; antipyretic
Brand Name: Panadol
Dose and Strength: 500 mg to 1000mg
Manufacturer: Haleon

SUSPECTED DRUG AND ITS PHARMACOLOGY

Class of Drug: Analgesic; antipyretic
Brand Name: Aequimol IV
Dose and Strength: Injection-150mg
Manufacturer: Aequitas Healthcare

Figure no 2. Aequimol IV 100 ml, 100

Mechanism Of Action:

Paracetamol has been used for over a century, but its exact mechanism remains unclear. It likely works in the brain by reducing prostaglandins and influencing serotonin, opioid, nitric oxide, and cannabinoid systemssuggesting multiple pathways act together.[11,12] Paracetamol is a simple painkiller and fever reducer, but unlike NSAIDs, it doesn't reduce inflammation. While it's often said to block COX enzymes that produce prostaglandins (chemicals causing pain and swelling), it doesn't act like NSAIDs. Prostaglandin H2 synthetase (PGHS), the enzyme making prostaglandins, has two parts: COX and POX. In two steps, COX makes PGG2, then POX converts it to PGH2. COX must remain "oxidized" to function, and paracetamol blocks this by acting at the POX site, stopping COX activity. It works best in low-peroxide areas like the brain, but less in inflamed tissues with high peroxide levels. Another theory suggests paracetamol acts on a brain-specific COX-1 form (once thought to be COX-3), explaining its effect on pain and fever without inflammation or platelet effects. However, this was based on dog studies, and in humans, this COX-1 form doesnt produce prostaglandins.[13]

Composition: Paracetamol 1000mg

Pharmacokinetics:

Plasma Concentration (Cmax): After infusion of 0.5 g and 1 g paracetamol, Cmax and AUC (inf) increased proportionally with the dose.

After correcting to 1 g dose:

Mean Cmax ratio = 0.98 ± 0.24
Mean AUC ratio = 0.94 ± 0.08

Volume of Distribution (VD):

V(d) were within the acceptable range (0.8–1.25).

Therapeutic dose:

>50 kg: 1 g every 4–6 hours; maximum 4 g daily.

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< 50 kg: 15 mg/kg every 4–6 hours; maximum 60 mg/kg daily.

Maximum Dose: usually 4 g daily.

Up to 6 g daily in palliative care or specialist pain services for 3–5 days (acute pain). Renal/Hepatic Impairment: Ensure doses are at least 6 hours apart.

Higher Dose Effects:

Overdose depletes glutathione.

Excess reactive metabolite binds to cell structures, causing liver damage.

Early treatment with methionine or N-acetylcysteine can prevent damage.

Half-Life:

Plasma half-life: 1.9–2.5 hours in healthy subjects.

Shortened by anticonvulsants.

Normal in mild liver disease, prolonged in decompensated liver disease.

Clearance:

Total body clearance: 4.5–5.5 mL/kg/min.[14,15,16]

General Dosing Information:

Acetaminophen infusion can be given once or repeatedly for pain or fever. No dose adjustment is needed when switching between oral and IV forms in adults and teens over 50 kg. The total daily limit includes all forms (IV, oral, rectal) and products containing acetaminophen—exceeding it can cause severe liver damage or death. Always stay within the safe daily limit.

Age group	Dose given every 4 hours	Dose given every 6 hour	Maximum single dose	Maximum total daily dose of acetaminophen (by all routes)
Adult's and adolescents (15 years and elder weighing>50kg	650 mg	1000 mg	1000 mg	4000 mg in 24 hours
Adults and adulescents (15 years and older) weighing<50kg	13.5 mg/kg	15 mg/kg	15mg/kg (up to 750 mg)	75 mg/kg in 2 Tours Sup to 3750 mg

Table.1. Dosing for Adults and Adolescents

Recommended Dosage:

For adults and adolescents 50 kg and over, acetaminophen infusion is typically 1000 mg every 6 hours or 650 mg every 4 hours. The maximum single dose is 1000 mg, with at least 4 hours between doses. Total daily intake from all sources must not exceed 4000 mg.

Recommended Dosage: Children, Children 2 to 12 years of age:

The recommended acetaminophen infusion dose is 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours, with a maximum single dose of 15 mg/kg, at least 4 hours between doses, and a maximum of 75 mg/kg per day.[17]

Age group	Dose given every 4 hours	Dose given every 6 hours	Maximum single dose	Maximum total daily dose of acetaminophen (by all routes)
Children 2 to 12 years of age	12.5 mg/kg	15 Mg/kg	15 mg/kg (up to 750 mg	75 mg/kg in 24 hours (up to 5750 mg)

Table. 2. Dosing for children

Route and Method of Administration:

Intramuscular route: Adults: 2 – 3 mm every 4 to 6 hours.

Children (2 -12 years / > 33 kg): Up to 2 ml every 4 to 6 hours.

Below 2 years of age: Half to 1 ml every 4 to 6 hours.

Intravenous route: Slow I.V Administration.

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Symptoms of Overdose:
Diarrhea
Sweating more than usual
Loss of appetite
Nausea or vomiting
Stomach pain or cramps
Swelling or tenderness in the upper stomach

Side Effects:
Allergic reaction (rash, swelling)
Flushing, low blood pressure, fast heartbeat (when given into a vein)
Blood disorders (low platelets or white blood cells)
Liver and kidney damage from overdose (can be fatal in severe cases)[18]

Contraindications:
Long Term Adverse Effects of Paracetamol:
Respiratory Effects: When paracetamol is broken down, it uses glutathione, which protects against harmful molecules (oxidative stress). Loss of glutathione may shift the immune system toward a Th2 response linked to allergies and asthma. Paracetamol may also disrupt the balance of inflammation-related chemicals like leukotrienes and prostaglandins.[19]
Gastrointestinal (GI) effects: Taking over 2–3 grams of paracetamol daily, especially long-term, may increase the risk of stomach bleeding. A UK study found lower doses were safe, but higher ones raised the risk, especially when combined with NSAIDs like ibuprofen.[20]
Hepatotoxicity: Some reports and small studies suggest that normal paracetamol doses (up to 4 g/day) may cause mild liver changes, but serious damage is rare. In one study, about half had no liver enzyme changes, and most others had only temporary increases that returned to normal.[21]
Renal Effects: Kidney injury occurs in about 1–2% of paracetamol overdose cases, usually alongside severe liver damage. It may be caused by toxic byproducts of paracetamol. Most recover within a month, with few requiring temporary dialysis[22]
Neurodevelopmental effects: A Norwegian sibling-controlled study found that prolonged maternal paracetamol use during pregnancy (>28 days) was linked to mild neurodevelopmental and behavioral issues in early childhood. No such link was found with ibuprofen, and no trimester-specific effects were observed.[23]
Drug Interactions of Paracetamol:
Warfarin(Coumadin): Paracetamol may enhance the anticoagulant effect of warfarin, increasing the risk of bleeding. Monitoring of INR is recommended, especially with prolonged or high-dose use.[24]
Antiepileptics(e.g., Carbamazepine, Phenytoin, Phenobarbital):These drugs can induce liver enzymes that convert paracetamol into its toxic metabolite, NAPQI, raising the risk of hepatotoxicity.[25]
Isoniazid:Isoniazid inhibits the formation of NAPQI, potentially reducing paracetamol's hepatotoxicity. However, this interaction can vary based on individual health conditions.[26]
Alcohol:Chronic alcohol consumption induces CYP2E1, increasing the production of NAPQI and heightening the risk of liver damage from paracetamol.[27]
Cholestyramine:Cholestyramine can reduce the absorption of paracetamol, potentially decreasing its effectiveness.[28]
Metoclopramide/Domperidone: These prokinetic agents can increase the absorption rate of paracetamol, leading to higher plasma concentrations.[29]
Grapefruit Juice: Grapefruit juice may alter the metabolism of paracetamol, affecting its bioavailability.[30]
Busulfan: Concomitant use with paracetamol can elevate busulfan levels, increasing the risk of toxicity.[31]
Uses of Paracetamol:
Pain Relief: Treats mild to moderate pain like headaches, muscle aches, back pain, toothaches, and menstrual cramps.[32]

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Fever Reduction: Lowers fever in conditions like colds, flu, and infections.[33]
Post-Operative Pain: Combined with NSAIDs or opioids for post-surgery pain.[34]
Arthritis/Musculoskeletal Pain: Used for pain in osteoarthritis and conditions without major inflammation.[35]
Headaches/Migraines: Effective for tension headaches and migraines.[36]
Children: First-line treatment for pain and fever, based on age and weight.[37]
Chronic Pain: Part of a treatment plan for conditions like fibromyalgia and lower back pain.
Opioid Combination: Sometimes combined with opioids (e.g., codeine) for enhanced pain relief.[38]

Result:

The Naranjo Adverse Drug Reaction (ADR) Probability Scale assesses the likelihood that an ADR is caused by a medication, with scores ranging from -4 to +13. A score of 4 indicates a "Possible" relationship between the drug and ADR. In this case, the patient developed anaphylaxis after the second dose of Inj. Paracetamol, and the Naranjo scale score of 4 suggests a possible link between the drug and the reaction. The reaction follows a recognized pattern for Inj. Paracetamol and could be influenced by the patient's underlying conditions.

Discussions:

Female patient of 40 years came to the hospital having chief complaint of fever. She was adviced Injection Aequimol. Inj. Aequimol 1g for three times a day by intravenous route was prescribed to her. After the 2nd dose of Inj. Aequimol, patient got itching all over the body, Concomitant medications in which advised tablet thiocolchicoside indicated for leg cramps and back pain. Patient has history of allergy of Ornidazole, Ofloxacin, Sulfa Drugs, Ibuprofen, Diclofenac. In given study the total Naranjo scale scored was 4 that described that given adverse reaction type was reported as possible adverse reaction. The study described that in present case study is dechallenge type and in replacement of this the treatment prescribed to the patient ie Inj. Pheniramine and inj. Hydrocartisone was administered to prevent allergic reaction. Further investigation is needed. Clearly, there remains considerable uncertainty regarding the chronic adverse effects of paracetamol use. The evidence base in each of the above sections relies mostly on observational and cohort studies, and so is prone to inherent biases. The positive associations found in these studies are generally weak, and often contradictory. Few RCTs have been performed but, when undertaken, usually give reassuring results. Further studies are required in many areas, but RCTs may be difficult to perform, either because they would need to be very large to detect the modest increases in risk seen in the observational studies, or because of the significant ethical issues of using placebo in patients in pain, as well as of conducting trials in children and pregnant women. The two areas in which the evidence is most convincing are hypertension and GI bleeding. A small BP rise of 4 mmHg would be clinically important at the population level, and the outcome of ongoing RCTs should clarify the reliability of this estimate. This may be particularly important in patients with angina or pre-existing hypertension. The fairly consistent evidence for GI bleeding associated with paracetamol use, along with its additive effect when combined with NSAIDs, may be less well known but similarly important. When considering prescribing paracetamol in the chronic setting it would seem wise to consider these adverse effects, based on current data, and discuss them with the patient. Indeed, in patients intolerant of NSAIDs, their next option would be opioid medication, which comes with risks of addiction, drowsiness and fatal accidental overdose. In summary, the average therapeutic effect for chronic pain syndromes is small, but there is accumulating evidence of clinically significant adverse effects in chronic use. Despite this, for patients who derive clear symptomatic benefit, or only take occasional therapeutic doses, the risks are probably very small. For this reason, paracetamol can be seen as the "least-worst option
which probably means that it will remain, for now at least, the first-line analgesic of choice..

II. CONCLUSION

The present case study highlights a suspected adverse drug reaction (ADR) to intravenous paracetamol (Inj Aequimol 1g TDS) in a 40-year-old female patient who developed generalized itching after the second dose. This reaction was managed by withdrawing the suspected drug (a dechallenge approach) and administering an antihistamine (Inj. Avil), resulting in symptomatic relief. The causality assessment using the Naranjo scale yielded a score of 4, categorizing the

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ADR as "possible." The temporal correlation between drug administration and onset of symptoms, along with a recognizable pattern of hypersensitivity, supports the likelihood of paracetamol being the causative agent. However, individual patient factors, including a history of drug allergies, may also have contributed. This underscores the importance of comprehensive patient history and close monitoring during paracetamol therapy, especially with IV formulations. Further investigation and pharmacovigilance are recommended to confirm causality and improve ADR management in clinical practice. So, further investigation is needed.

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