

**Research Article** 

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# **Adverse Drug Reaction Reported To Injection Calcium Gluconate**

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#### ARTICLE INFO

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#### ABSTRACT

In the modern day, adverse drug reactions (ADR) are one of the most important subjects to evaluate. The World Health Organization (WHO) defines an adverse drug reaction (ADR) as any unpleasant and inadvertent reaction to a drug that happens at dosages used in humans for disease prophylaxis, diagnosis, or therapy; or for altering physiological function. This definition intentionally leaves out therapeutic failures, overdoses, drug abuse, noncompliance, and medication errors. Furthermore, it has been considered a noteworthy adverse event that arises from a medical product-related intervention. On the other hand, side effects are typically connected to a drug's therapeutic properties and can be both advantageous and detrimental. Therefore, it is possible to argue that an adverse drug reaction (ADR) is defined as an adverse or undesired reaction that occurs after taking a medication or a combination of medications under normal use circumstances. Nonetheless, a number of ADR types, including type A, type B, and type C adverse responses, have been documented. types of negative drug reactions Adverse reaction types can be categorized under two primary headings: typical adverse drug reactions (ADRs) such as type A and type B reactions, and uncommon ADRs such as type C, D, and E reactions. Adverse reactions of type A have frequently been linked to dosage, which amplifies the drug's typical therapeutic impact. Moreover, type A ADRs have been linked to the pharmacokinetic or pharmacodynamic aspects of the medications. Genetic variations may be responsible for the pharmacokinetic causes of type A reactions, which in turn result in ADRs.

# **INTRODUCTION**

In the modern day, adverse drug reactions (ADR) are one of the most important subjects to evaluate .The World Health Organization (WHO) defines an adverse drug reaction (ADR) as any unpleasant and inadvertent reaction to a drug that happens at

dosages used in humans for disease prophylaxis, diagnosis, or therapy; or for altering physiological function. This definition intentionally leaves out therapeutic failures, overdoses, drug abuse, noncompliance, and medication errors. Furthermore, it has been considered a noteworthy

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adverse event that arises from a medical productrelated intervention. While side effects are typically connected to a drug's therapeutic actions, adverse effects, Furthermore, it has been considered a noteworthy adverse event that arises from a medical product-related intervention. While side effects are typically associated with a drug's therapeutic activity and can be both useful and harmful, adverse effects are defined as an overstatement of the intended therapeutic impact and constitute a portion of ADR. Therefore, it is possible to argue that an adverse drug reaction (ADR) is defined as an adverse or undesired reaction that occurs after taking a medication or a combination of medications under normal use circumstances. Nonetheless, a number of ADR types, including type A, type B, and type C adverse responses, have been documented .which happen as an overstatement of the intended therapeutic impact, are a component of ADR. types of negative drug reactions Adverse reaction types can be categorized under two primary headings: typical adverse drug reactions (ADRs) such as type A and type B reactions, and uncommon ADRs such as type C, D, and E reactions . Adverse reactions of type A have frequently been linked to dosage, which amplifies the drug's typical therapeutic impact. Moreover, type A ADRs have linked to the pharmacokinetic been or pharmacodynamic aspects of the medications. Genetic variations may be responsible for the pharmacokinetic causes of type A reactions, which result ADRs. Furthermore, in turn in pharmacokinetic abnormalities brought on by hepatic disorders have been shown to result in ADR by altering the distribution and metabolism of medicine. Pharmacokinetic differences have been hypothesized to be caused by the medicines' elevated half lives combined with lower glomerular filtration rates (GFR). Furthermore, side effects have been noted with medications that the kidneys frequently reject. ADRs have also

been reported to be brought on by changes in apparent volume of distribution, inadequate renal perfusion, and reduced absorption brought on by mucosal oedema. Therefore, we are doing this study with the aim of understanding the adverse medication reaction by drug. When addressing ADRs in patients, healthcare professionals make judgments about therapy based on an informal assessment of causality. Regulatory bodies review reports of spontaneous adverse drug reactions (ADRs), and causality analysis can support signal detection and risk-benefit calculations for medications. Since algorithms are organized systems created especially to identify an ADR, they ought to be able to decide on causation more objectively. Four fundamental concepts form the foundation of the objective causal assessments: temporal eligibility, challenge and outcome, challenge and outcome again, and confounding circumstances. The Jones algorithm, the Naranjo algorithm, the Yale algorithm, the Karch algorithm, the Begaud algorithm, the Australian ADR advisory committee, the World Health Organization-Uppsala Monitoring Center (WHO-UMC) criteria, and many other algorithms and decision aids have been published. The Jones algorithm, the Naranjo method, the Yale algorithm, the Karch algorithm, the Begaud algorithm, the Australian ADR advisory committee, and the World Health Organization-Uppsala Monitoring Center (WHO-UMC) criteria are only a few of the documented algorithms and decision aids. There are variances and similarities between each of these algorithms. The WHO-UMC method was created as a useful tool for evaluating case reports after consultation with National Centers involved in the Program for International Drug Monitoring. It is essentially a combination evaluation that considers the case history's clinical-pharmacological elements as well as the caliber of the observational record.



# Case Report on Adverse Drug Reactions (ADRs)

In pharmacovigilance, a case report is a notification about a patient who may have been exposed to a medication that caused an adverse medical event or abnormal laboratory test results. It is crucial to emphasize that healthcare professionals, even in the absence of all necessary information, should nevertheless report adverse drug reactions (ADRs).

### Consumer

An individual who is not a member of the medical community, such as a patient's friend or relative.

#### **Drug Abuse:**

Abuse of drugs refers to the deliberate, excessive use of medications, whether it be intermittent or continuous, and it is accompanied by negative health or psychological effects.

#### **Accelerated Reporting:**

This refers to the reporting of a significant negative response to the Board as soon as possible, and in no more than seven calendar days.

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This refers to the reporting of a significant negative response to the Board as soon as possible, and in no more than seven calendar days. Individuals with medical qualifications, such as doctors, dentists, pharmacists, nurses, or community health officers, are referred to as healthcare professionals.

### Marketing Authorization Holder:

An entity that may or may not be the product's maker that has been granted permission by the appropriate authorities to market pharmaceuticals, medical supplies, or cosmetics in Sierra Leone or any other nation. A new drug is defined as a **Suspected Drug Details:** 

chemical or biologically active pharmaceutical ingredient that has never before received a marketing clearance in India to be used as a component of any pharmaceutical product.

### Misuse Situations:

These occur when a medication is purposefully and inappropriately utilized in ways that are not permitted by the approved product information.

# The National Pharmacovigilance Center is known as NPC.

Exposure at work Exposure:-due to one's professional or non-professional vocation, to a pharmaceutical product Off-label application circumstances in which a medication is purposefully taken for a medical purpose that does not comply with the approved product information.

#### **Overdose:**

The administration of a medication in an amount that exceeds the maximum recommended dose as stated in the approved product information, either individually or cumulatively.

### **MATERIAL AND METHODS:**

#### **Title of Study:**

Investigation of Adverse Drug Reaction A case report of drug eruption with a positive Dechallenge-Rechallenge test caused by injection of calcium gluconate.

The current investigation was carried out at Manipal Hospital Baner.

#### **Research Framework**

**Case report:** 

observational research on a medication's adverse effect.

### The population under study's source

A patient admitted to Baner's Manipal Hospital CASE STYDY

Name/Intials: KT

Age: 69years

Sex: male

Hospital/Clinic: Manipal Hospital Baner-Pune

### 1. Drug: Calcium Gluconate



Dose:10% Route: Intravenous(IV) Batch No:22062 Expiry Date:31/3/25 Frequency: STAT Therapy dates-Date Started:23/10/22 Date stopped:23/10/22 **Concomitant Medical Product:-**25% Dextrose **Therapy dates-**Date Started:22/10/22 Date stopped:22/10/22 Suspected Adverse Drug Reaction:

Event /Reaction start date: 23/10/22 Event/Reaction stop date:23/10/22

# Adverse Drug Reaction:-

Injection Calcium Gluconate 10% in 100ml NS was prescribed to the patient, administered by infusion pump. After 2min of ongoing administration patient developed a burning skin , patch around the prick area.

Infusion was stopped.

No Swelling accompanied with burning patch.

### Action Taken after reaction :

Medicine was given in vein of another upper limb. Reaction reappeared after reintroduction of suspected medication :No

### **Reporter Details:**

Name: Dr.Akshay Khirade

Address: Clinical pharmacologist, Manipal Hospital.

Contact:9604020940

Occupation:Clinical Pharmacologist

Date of this Report:25/10/22

On 22/10/22 first Sodium Bicarbonate is Administered to the Patient adverse reaction is occurred so next day 23/10/22 Calcium Gluconate is administered then after 2min developed a burning skin ,patch around the prick area and Infusion was stopped. After that Medicine was given in vein of another upper limb. Drug and Pharmacology Calcium Gluconate (Rx, OTC) Brand and Other Names:Gluconate, Ca Classes: Antidotes, Other; Calcium Salts Dosage Forms & Strengths in Adults Injectable solution 100mg/mL (10%) Tablet 50mg 500mg 650mg Capsule 500mg



#### Tambe Ayush K., Int. J. of Pharm. Sci., 2024, Vol 2, Issue 3, 828-836 |Research

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### **MECHANISM OF ACTION**

Extracellular potassium elevations may result in heart arrhythmias, which may then lead to cardiac arrest and death. Stabilizing cardiac cell membranes is the function of calcium gluconate in the treatment of hyperkalemia. Any patient who with hyperkalemia with EKG presents indicating abnormalities. hyperkalemic a emergency, should receive calcium immediately. By raising the threshold potential of cardiac myocytes, elevated potassium levels destabilize cardiac membranes. The threshold to reestablish the transmembrane voltage gradient is lowered by calcium.mild supplementing with (calcium ionized at 1-1.2 mmol/L)

Handling of non-life-threatening signs and symptoms

IV: 1-2 g over 2 hours; PO: 1-3 g/day in divided doses; oral replacement therapy may be explored and given on an outpatient basis

#### Severe (ionized calcium <1 mmol/L)

- Without seizure or tetany: 0.5 mg/kg/hr IV; may be increased to 2 mg/kg/hr; not to exceed 3-4 g IV over 4 hours
- Hypocalcemic tetany: 100-300 mg elemental calcium (~3 g calcium gluconate) IV over 5-10 minutes, followed by continuous IV infusion at 0.5 mg/kg/hr (may be increased to 2 mg/kg/hr)
- Monitor serum calcium q4-6hr to maintain serum calcium levels

#### **Adverse Effects**

- Frequency Not Defined
- Bradycardia
- Hypotension
- Headache



- Constipation
- Diarrhoea
- Flatulence
- Nausea
- Vomiting
- Hypomagnesemia
- Hypophosphatemia
- Extravasation necrosis

#### Warnings

#### Contraindications

- Hypersensitivity
- IM/SC administration
- Ventricular fibrillation during CPR
- Hypercalcemia
- Digoxin poisonings

## IMAGE

• Sarcoidosis

### Cautions

- Hepatic or renal impairment, cardiovascular disease, acidosis, history of renal calculi
- Cardiac arrest may occur
- Calcium gluconate injection contains aluminium, up to 100 mcg per litre
- Constipation, bloating, and gas may occur with oral administration
- Use caution in patients with severe hyperphosphatemia
- Adult and Pediatric Advanced Life Support programs no longer recommend routine calcium for CPR[20].

BRAND	FORM	PILL IMAGE
calcium gluconate intravenous	100 mg/mL (10%) vial	
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### RESULT

The study's findings highlighted the necessity of ADR reporting at tertiary care facilities in order to assist in determining the benefit-risk ratio of medications. This investigation led to the

conclusion that the adverse medication reaction described in the case study may be of a certain kind. It demonstrates the assessment of causality between a suspected medication and an adverse drug reaction.



l	Naranjo Ala	Yes	No	Do Not Know	Score
	Question U.m.2	+1	0	0	0
1 11	Are there previous conclusive reports on this reaction?	+2	-1	0	+2
2	Did the adverse event appear after the suspected drug was administered	+1	0	0	+1
5.	specific antagonist was administered?	+2	-1	0	-1
A. I	Did the adverse event reappear when the drug that could on their own	-1	+2	0	0
	Did the reaction reappear when a placebo was given?	-1	+1	0	+1
	Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
	Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	Ø
	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	D
).	Was the adverse event confirmed by any objective evidence?	+1	0	0	+1

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

Scoring for Naranjo algorithm

>9 = definite ADR

5-8 = probable ADR

1-4 = possible ADR

0 =doubtful ADR.

69 year IPD patient prescribed INJ calcium gluconate in 100ml of NS administered by infusion pump after 2min of ongoing administration patient developed burning skin patch around the prick area.

The patient reported and measure naranjo scale and the total score of naranjo scale was 4, that show patient reported with possible adverse drug reaction.

### DISCUSSION

This spontaneous case, which was received on October 23, 2022, involved a 69-year-old male patient whose skin began to burn after receiving intravenous calcium gluconate. Commencing on October 23, 2022, and ending on October 23, 2022, was the concurrent drug that included 25% dextrose. In this instance, the infusion was halted after two minutes because the patient's skin and patches were burning [Dechallenge]. Following that, medication was injected into the vein of a different upper limb [Rechallenge].

#### CONCLUSION

It has been believed that pharmacokinetic and pharmacodynamic differences in drug products are the cause of adverse medication responses. We came to the conclusion in this study that injection calcium gluconate is linked to the adverse drug reaction that is currently being reported. Therefore, in this investigation, the suspected drug was initially decoked and then the medication was reconstituted.



## LIMITATION

The current study has some limitations. Firstly, the patient's past medical history was withheld, and the patient's second diagnosis was not disclosed in the ADR form. The third is the lack of an available investigative report on past medication history, allergies, and family history.

## ACKNOWLEDGMENT

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