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A Retrospective Study on Drug Induced Complications Among Different Age Groups

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ABSTRACT

Aim And Objective: This study is aimed to perform a retrospective study on drug induced complications among different age groups.

Methodology: This retrospective study was conducted at Aware Global Hospital in Hyderabad aimed to investigate the prevalence of drug induced complications among them. Over a 6 months period, data was collected from 85 patient cases from general medicine department.

Results: The research findings reveal a higher drug induced complications incidence in males (54%) than females (46%), predominantly drug induced hypoglycemia (27.05%). According to WHO classification of age groups elderly age group (60-74 years) accounted for maximum DID's (45.58%). Hypoglycemia (27.05%), hypersensitivity (11.80%), hyponatremia (8.23%), hyperglycemia (8.23%), hepatopathy (7.05%), cough (5%), gastritis (3.52%), AKI (2.4%), parkinsonism (2.4%), pedal edema (2.4%), oral bleed (2.4%) was some of the drug induced complications involved. The 61-70 age group faces a higher risk (31%), often linked to comorbidities.

Conclusion: The study concluded that a total of 85 patients with drug induced complications has been found a peak in the age group 61-70, with a higher incidence in males compared to females. Usage of anti-diabetic agents, anti-hypertensives, antibiotics, corticosteroids, NSAID's, anti-tubercular agents, anti-coagulants, anti-platelets, anti-psychotics were usually involved in causing complications.

Keywords: *Drug induced complications, NSAID's, hypoglycemia, hypersensitivity.*

1. INTRODUCTION

A drug-induced disease is a result of an adverse effect of medication usage, leading to major health consequences of mortality or significant illness, that requires medical approach and or hospitalization. This can occur due to anticipated or unanticipated reactions to the drug. [1] Universally, adverse drug reactions (ADR's) are a significant cause to substantial illness and death. Researches have shown that ADRs occur in a notable percentage of cases, varying from 0.16% to 15.7%. [2]

Epidemiology plays a crucial role in understanding drug-induced diseases. In the setting of pharmaceuticals, epidemiology is vital for examining the efficacy, safety, and utilization of drugs in real-world. By applying epidemiological propositions, researchers can shed light on the therapeutic benefits and potential hazards related with specific treatment, eventually informing our understanding of morbidity and mortality outcomes. Drug-induced diseases (DID's) remain a tenacious concern for both patients, physicians and other healthcare professionals. [3]

Drug-induced diseases can be grouped into anticipated or un-anticipated effects.

Predictable effects:

- Predictable effects are the addition of pre-established normal pharmacological effect of a therapeutic agent.

Examples:

- Drugs like Insulin and Sulfonylureas causes hypo-glycemia.
- Drugs like Anticoagulants and Anti-platelets causes bleeding, hemorrhages.

Unpredictable effects:

➢ Unpredictable effects are the events which are un-associated to therapeutic effects of the drug.

Examples:

- Drugs like Amiodarone may cause lung damage in some individuals. [4]

❖ **Cardiovascular System:**

Cardiotoxicity induced by drugs is possibly serious adverse effect. This results in cardiac muscle dysfunction, reduced left ventricular ejection fraction, fibrosis. It may result from following underlying mechanisms like inflammation, oxidative stress, alteration in ion channels and electrical conduction, cellular energy impairment and direct myocardial injury.

Examples of banned drugs due to plausible adverse effects:

a) Antineoplastic agents (Anthracyclines, Cyclophosphamide)
b) Neurological or psychiatric agents
c) Antiretroviral agents (Zidovudine)
d) Antidiabetic agents (Rosiglitazone)
e) Illicit drugs (Alcohol, Cocaine, Amphetamine) [5]

❖ **Neurological Conditions:**

Drug-induced Neurological side effect is described as a new onset of neurological syndromes or disorders caused by medication. These effects can result as follows:

1. Central Nervous System (CNS): -
    - Brain
    - Spinal cord

2. Peripheral Nervous System (PNS): -

Resulting symptoms may include:

➢ Motor impairment:
    ▪ Loss of coordination
    ▪ Muscle weakness
➢ Sensory disturbances:
    ▪ Numbness
    ▪ Tingling
➢ Altered consciousness:
    ▪ Confusion
    ▪ Loss of consciousness
➢ Seizures
➢ Paralysis

These symptoms may vary in severity and daily functioning. Precise diagnosis and management are crucial to alleviate drug-induced neurological side effects. [6]

❖ **Pulmonary System:**

Drug-induced respiratory diseases enclose various pathophysiologic conditions, making the diagnosis challenging. Adverse pulmonary reactions are infrequent but serious, often needs medical intervention.

Central nervous depression or respiratory neuromuscular blockade may cause apnea.

Benzodiazepines may produce respiratory depression than barbiturates, this induces additive or synergistic effect when taken

in combination or with any other respiratory depressant drugs.

Combination of IV diazepam along with phenobarbital for the treatment of seizures often requires ICU admission for mechanical ventilation.

Rapid IV administration of IV benzodiazepine increases the risk of apnea, even without using other respiratory depressants.

Epidemiologic Findings:

Usage of acetaminophen increases the risk of asthma and COPD whereas, the usage of aspirin combined with ibuprofen does not show any such associations.

Administration of acetaminophen in infants at the age of 6-7 increases the prevalence of asthma by 46%.

- Examples of familiar drug-induced respiratory events:
    - Bronchoconstriction or Bronchospasm is a most common respiratory condition which is caused by the usage of various drugs
    - Risk of aspirin-induced bronchospasm increases with age after 30 usually. [7]

❖ **Renal System:**

Drug-induced nephrotoxicity is a major clinical complication, with up to 60% of the acute kidney injury (AKI) cases attributed to medication.

Mechanisms:

1. Drugs leading to decreased GFR and alterations in hemodynamic functioning:
    - Angiotensin converting enzyme inhibitors (ACE)
    - Tacrolimus
    - Angiotensin receptor blockers (ARBs)
    - Cyclosporine
    - Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

2. Drugs associated with crystal nephropathy:
    - Ampicillin
    - Triamterene
    - Ciprofloxacin
    - Methotrexate
    - Sulphonamides
    - Ganciclovir
    - Acyclovir

3.Drugs that provoke rhabdomyolysis:
    - Alcohol
    - Statins

4. Drugs inducing acute interstitial nephropathy and tubular cell toxicity:
    - Aminoglycosides
    - Acyclovir
    - Amphotericin B
    - Vancomycin
    - Cisplatin
    - Sulphonamides
    - Rifampicin

- Beta-lactams
- Quinolones
- Contrast agents

5. Drugs associated with fibrosis and chronic interstitial nephritis:

- Long-term usage of acetaminophen
- Lithium
- Aspirin
- Diuretics [8]

❖ **Gastrointestinal System:**

Drug-induced gastrointestinal (GI) symptoms and endoscopic pathology are usual problems faced by patients in clinical practice, often drug induced GI disorders resembles other GI conditions like inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS). Failure to identify drug-related clinical features can lead to unwanted investigations and medical management. Drugs which are causing GI symptoms are as follows:

Drugs causing GI symptoms by altering the enteric physiology includes anticholinergic medication which results in constipation.

Drugs like non-steroidal anti-inflammatory agents induces gastrointestinal ulcers by damaging GI epithelium tissue toxicity.

Disruption of intestinal microbiota leads to clostridium difficile infection which is caused by antibiotics and also metformin by unspecified pathological mechanisms.

The active pharmaceutical ingredient (API) and other inactive excipients present in any dosage form may result in GI complications.

➢ Examples:

- Nausea and vomiting are precipitated by mechanisms which takes place outside the GI tract. [4,9]

❖ **Hematopoietic System:**

The idiosyncratic medication-induced blood disorders are rare but serious, and may vary in incidence.

Hematologic conditions caused by drugs includes the following:

1. Drugs causing anaemia

➢ Drugs like chloramphenicol, sulphonamides, carbamazepine causes anaemia by decreasing the production of red blood cell (RBC) in bone marrow.

➢ Drugs like primaquine, sulphonamides, penicillin induces anaemia by destroying RBC due to G_6PD enzyme deficiency.

2. Drugs causing leukopenia

➢ Drugs like methimazole, phenylbutazone, clozapine reduces the count of WBC by increasing the risk of infections.

2. Drugs causing thrombocytopenia

Drugs like heparin increases the risk of bleeding by decreasing the platelet count.[10]

Methodology

➢ **Study Design:** Retrospective study.

➢ **Sample Size:** This study includes 80 patients.

➢ **Study Site:** This study was conducted in the Department of General Medicine Gleneagles Aware Hospital, L.B. Nagar, Hyderabad, Telangana.

➢ **Study Period:** This study was conducted for 6 months.

➢ **Study Criteria:**

❖ **Inclusion Criteria:**

- Patients of both genders are included
- Patients in age of 20-90 years

- Patients with comorbid conditions
- Patients with drug-induced conditions

❖ **Exclusion Criteria:**

- Paediatric patients.
- Pregnant patients.
- Patients under gone surgeries.
- Patients on other medication systems, unknown drugs, natural products
- ADRs related to overdose and poisoning cases

➢ Ethical Statement: Study will be conducted only after the approval of hospital ethical committee.

➢ Tool: Patient case reports, lab investigation reports.

➢ Data Collection: All the relevant and necessary data will be collected from patient record and laboratory records.

➢ **Statistical Tools:**

T-test

Anova

Chi square test

2. RESULTS

Table 1: Prevalence of DIC's by age and gender with an age interval of 10 years

S.No	Age	No of patients with DIC's	No of Males	No of Females
1.	21-30	6	1	5
2.	31-40	8	6	2
3.	41-50	8	2	6
4.	51-60	21	13	8
5.	61-70	26	13	13
6.	71-80	13	9	4
7.	81-90	3	2	1

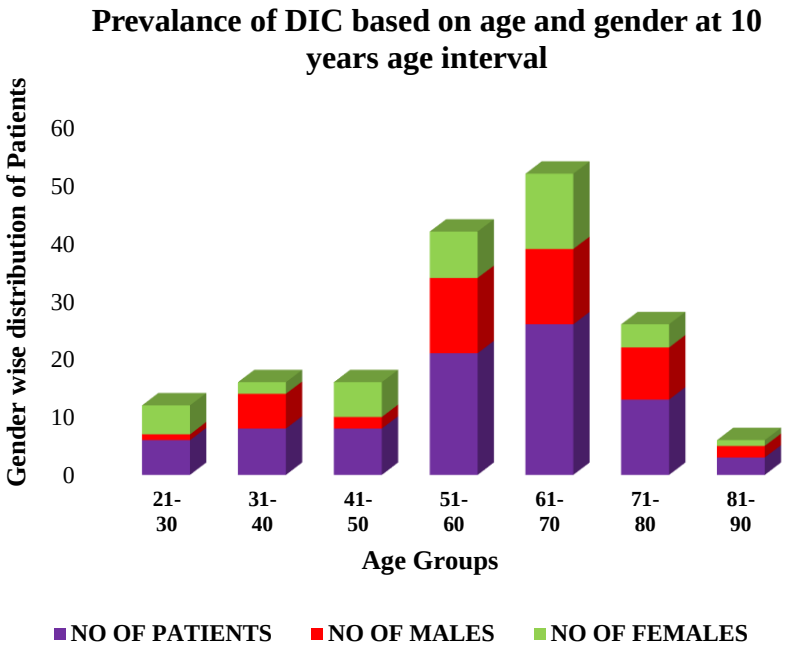

Figure 1: Stacked column showing prevalence of DIC's by age and gender with an age interval of 10 years

Among the study population the age group of 61-70 has the most drug induced complications.

Table 2: Types of DID's distribution among study population

S.NO	DRUG INDUCED COMPLICATIONS	NO OF PATIENTS WITH DID's	PERCENTAGE
1.	Hypoglycemia	23	27.05%
2.	Cough	4	5%
3.	Gastritis	3	3.52%
4.	Acute Kidney Injury	2	2.4%
5.	Parkinsonism	2	2.4%
6.	Pedal Edema	2	2.4%
7.	Hyperglycemia	7	8.23%
8.	Hypersensitivity	10	11.80%
9.	Hepatopathy	6	7.05%

10.	Hyponatremia	7	8.23%
11.	Oral Bleed	2	2.4%
12.	Others	16	19%

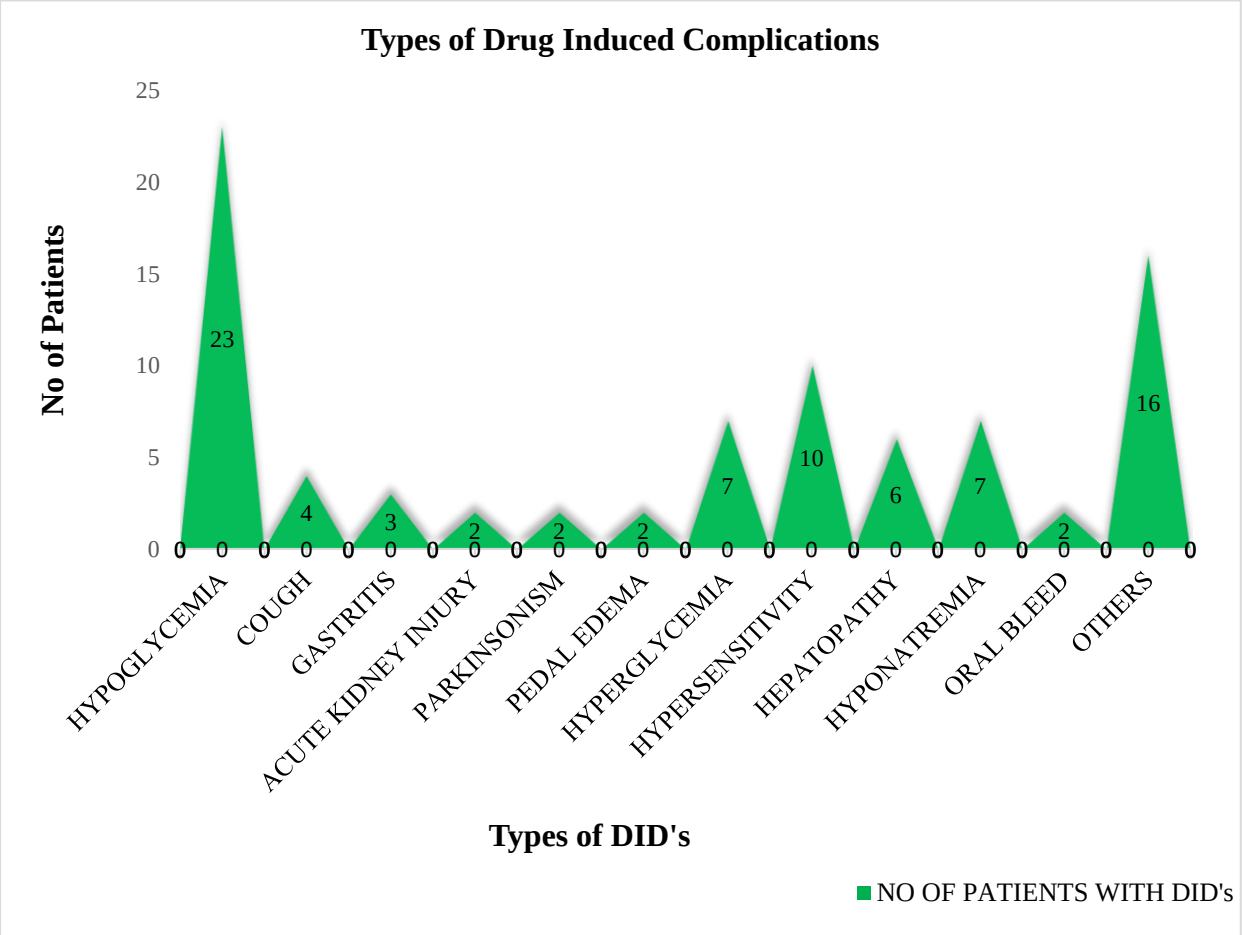

Figure 2: Area graph showing types of DID's

In the study population drug induced hypoglycemia was found in about 23 individuals and AKI, parkinsonism, pedal edema and oral bleed was found in 2 patients.

3. DISCUSSION

In the previous study conducted the analysis showed that out of 1385 patients included in the study, 243 (44.5%) were males and 303 (55.5%) were females in the drug induced diseases. [11] whereas, in the current study carried out it has been concluded that out of the sample size of 85 patients with drug induced complications 46 (54%) were found to be males and 39 (46%) were found to be females.

In the current study conducted it has been analyzed that out of the study population of 85 patients with the drug induced complications the rate of geriatrics (>65 years) were found to be 30 patients (35.29%), adults (21-64 years) 55 patients (64.7%) and the intervention of common DID's were hypoglycemia (27.05%), hypersensitivity (11.8%), hyperglycemia (8.23%), hyponatremia (8.23%), hepatopathy (7.05%), cough (5%), gastritis (3.52%), AKI (2.4%), pedal edema (2.4%), parkinsonism (2.4%), oral bleed (2.4%), others (19%). The frequently involved drugs were hypoglycemic agents, anti-hypertensive agents, antibiotics, steroids, NSAID's, anti-tubercular therapeutic agents, anti-coagulants, anti-platelets, anti-

psychotics and others whereas, in the previous study conducted the reports showed that the rate of geriatrics (>65 years) 53.99% and adults (18-64 years) 37.79% and the common DID's were gastritis (7.43%), diarrhea (5.92%), anemia (4.79%), hypotension (2.77%), hepatic dysfunction (2.69%), hypertension (1.51%), myalgia (1.05%), renal dysfunction (1.01%) and the commonly involved drugs were anti tubercular therapeutic agents (ATT), anti-retro viral agents (ART), injection ceftriaxone, steroids, Non-steroidal anti-inflammatory drugs (NSAID's), anti-neoplastic drugs and antimicrobial agents. [12]

In the earlier study conducted the analysis showed that out of 394 patients were started on ACE inhibitors, among them 57.1 (225) were males, 93.7% (369), 95.4% (376) had a past medical history of hypertension, 48.47% (192) had a past medical history of diabetes and the incidence of cough induced by ACE inhibitors was 24.1% [13] whereas, in the current study carried, out of 85 individuals incidence of cough was 0.04% (4) among them 25% (01) were male, 25% (01) were female who were taking ACE inhibitors for hypertension.

In the previous study, conducted for about 30 years the analysis showed out of 906 cases of parkinsonism with 108 (11.9%) were attributed to drug-induced parkinsonism. Typical antipsychotic agents were the primary agents that caused drug induced parkinsonism whereas, atypical antipsychotics were rarely involved [14] whereas in the current retrospective study out of 85 cases of DID, 2 (0.02%) were drug induced parkinsonism among them typical antipsychotics and atypical antipsychotics were equally involved in causing drug induced parkinsonism.

In the previous study involving 102 patients has revealed 61 were females, 41 were males with an average age of 72 years examined drug-induced hypoglycemic coma. 92 patients had type II diabetes mellitus, while 10 patients had type I diabetes mellitus, the lowest blood glucose level was found to be 32mg/dl. In the group of 102 patients 99 patients affected with hypoglycemic coma outside the hospital, while 3 developed in the course of hospitalization. Hypoglycemic coma occurred in patients treated with glyburide, insulin and combined therapy with insulin + metformin, insulin + glyburide or glyburide + metformin [15] whereas in our current analysis out of 85 patients with DID's, 23 were found to be drug-induced hypoglycemia in which 12 were male and 11 were female with an average age of 65 years examined drug-induced hypoglycemic coma. All the 23 patients had a past medical history of type II diabetes mellitus, the lowest blood glucose level was found to be 20mg/dl. In the group of 23 patients 21 developed hypoglycemia outside the hospital and 2 patients affected with hypoglycemia during the course of hospitalization. The common drugs that induced hypoglycemic coma are insulin, glimperide + metformin, glimperide, pioglitazone + sitagliptin.

In the previous study conducted 125 patients reported about an incidence rate of AKI was 8% with 10 individuals was detected. Particularly, the majority (80%) of AKI cases occurred in the older age group (45-65 years), with a greater prevalence among males (60%) compared to females (40%). Additionally, 40% of AKI patients had past history of hypertension, increasing their vulnerability to AKI. Diagnosis was based upon changes in laboratory parameters, especially serum creatinine levels [16] whereas, in the ongoing study out of 85 subjects reported an incidence of AKI was about 2.3% with 2 patients. Especially the majority of AKI cases occurred in older age groups (45-60 years) with a greater prevalence among males (100%) compared to females (0%). Moreover, AKI patients had a past medical history of hypertension increasing the risk of AKI. Diagnosis was based upon the levels of serum creatinine.

In the prior research conducted for 4 years in 253 individuals the analysis showed that 24 (9.48%) individuals have experienced drug-induced liver injury and it has been found that there is no notable relationship between drug-induced liver injury and various risk factors such as hepatitis B infection, hepatitis C infection, HIV infection, chronic alcohol consumption, and pre-existing chronic tuberculosis [17] whereas, considering our present analysis revealed that out of 85 study population of drug-induced complications, 6 (7.05%) were drug-induced liver diseases. The risk factors involved were pre-existing chronic tuberculosis infection and alcohol consumption were found.

In the previous study conducted for a period of 6 years it has been found that out of 6489 patients, 155 (2.4%) experienced drug-induced thrombocytopenia. The risk factor for drug-induced thrombocytopenia is treatment with cefoperazone/sulbactam for about greater than 14 days and the initial platelet level was about $<200*10^9$/L, the daily dose of cefoperazone/sulbactam was greater than or equal to 6 grams, total bilirubin level was greater than 21 umol/L, aspartate aminotransferase level > 35 U/L and the uasage of non-invasive ventilation. These factors were associated with increased risk of developing drug-induced thrombocytopenia [18] whereas, in our current retrospective study it has been reported that in an about 85 subjects, 1 (1.17%) individual has experienced drug-induced thrombocytopenia and the causative drug involved was cefoperazone/sulbactam, the patient was treated for about 4 days with this drug. The beginning platelet count was 1.75 lakhs/ul, and the platelets was declined gradually in about 4 days after the drug with causative drug (0.82 lakhs/ul). The daily dose of cefoperazone/sulbactam was 3 grams, total bilirubin level was 35.36 umol/L, AST level was 74U/L. Finally, it has been concluded that these factors have contributed in increasing the risk of thrombocytopenia.

4. CONCLUSION

Our study is a retrospective study conducted at Aware Gleneagles Global Hospital, Bairamalguda, Hyderabad, Telangana, India. A total of 85 patients with drug-induced complications has been considered for our study.

- A total of 85 patient cases were collected.

- Gender wise distribution of patients during the study period showed that the maximum number of male patients [46 (54%)] and female patients [39 (46%)] has experienced drug-induced complications.
- Age wise distribution of the patients, revealed that the maximum number of patients during the study period were in the age group of 61-70 years [26 (31%)] and the minimum number of patients were in the age group of 81-90 years [3 (3.50%)].
- Organ system wise distribution in patients with drug-induced complications, revealed that the complications related to endocrine system [31(36.47%)] has been observed in maximum number of patients and the complications related to hematological system [1(1.07%)] has minimum number of patients.
- The drug-induced complication in the study population were hypoglycemia [23(27.05%] followed by others [16(19%)], hypersensitivity [10(11.80%)], hyponatremia [7 (8.23%)], hyperglycemia [7 (8.23%)], hepatopathy [6 (7.05%)], cough [4(5%)], gastritis [3(3.52%)], AKI [2(2.4%)], parkinsonism [2(2.4%)], pedal edema [2(2.4%)], oral bleed [2(2.4%)].
- Distribution of comorbidities in patients with DID's in the study population showed that patients with more chronic conditions has highest percentage [69 (81.18%)] of drug induced complications.
- Category wise distribution of drugs causing DID's includes anti-diabetics [24(28.23%)], anti-hypertensives [14(16.47%)], antibiotics [9(10.58%)], corticosteroids [7(7.81%)], NSAID's [7(7.81%)], anti-tubercular agents [6(7.50%)], anti-coagulants [4(5.0%)], anti-platelets [3(3.80%)], anti-psychotics [3(3.80%)] and others [8(9.0%)].
- Usage of therapy in patients with DID's among study population monotherapy [51(60%)] was highest than dual therapy [34(40%)]
- Distribution of drug-induced allergies in a study population was greater with cephalosporins.
- Distribution of steroid induced hyperglycemia has been maximally seen in patients treated with dexamethasone [5(71.50%)]

Distribution of age groups according to WHO classification in study population revealed the highest number of DID's were seen in the age group of 60-74 years [31(45.58%)]

Conflict of interest: Nil

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