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# A Case Report on Paracetamol Induced Generalized Fixed Drug Eruptions

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**Dr. Suresh Sake[1], Dr. C Sugunakar Raju*[1], Dr. Parveen[1], P. Mohammed Shafi[2], K. Sarath Chandra Reddy[3], Lakkireddy Kavya[4]**

*[1]Consultant Dermatologist in Internal Medicine, Rural Development Trust Hospital (RDT), Bathalapalli, Anatapur, India – 515661*

*[1]Assistant professor, Department of Pharmacy Practice (Pharm D), P Rami Reddy Memorial College of Pharmacy, Kadapa, India – 516003*

*[1,2,3,4]Department of Pharmacy Practice (Pharm D), P Rami Reddy Memorial College of Pharmacy, Kadapa, India –516003.*

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**ABSTRACT**

Generalized Fixed Drug Eruptions (FDE) is a type of drug-induced skin reaction pattern that characteristically recurs at the face, chest, same skin or mucosal site. Paracetamol is one of the common drugs prescribed as analgesic–antipyretic agent in all age group of patients. FDE is a well-reported, but uncommon side-effect of paracetamol, usually the classic, pigmenting type most commonly found in children and adolescents. We present a case of 10 years old male patient who developed Generalized FDE over the back, abdominal region, face and chest region and total body following paracetamol use.

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## INTRODUCTION

Paracetamol also known as acetaminophen is one of the most popular and most commonly used analgesic and antipyretic drugs around the world and available without a prescription, both in mono- and multi-component preparations. It is a drug of choice in patients in whom application of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) are contraindicated, e.g., in the case of gastric ulcers, hypersensitivity to aspirin, impairments in blood coagulation, in pregnant women, nursing mothers and children with fever accompanying a disease[1]. The central analgesic action of paracetamol is like aspirin, i.e. it raises pain threshold but has weak peripheral anti-inflammatory component[2], Paracetamol may act by inhibiting COX-3 in CNS, which is involved in pain perception and fever but not in inflammation. Another explanation for its lack of anti-inflammatory action is that it poorly inhibits COX-1 in the presence of superoxides which are generated at inflammatory sites by leukocytes[3]. Paracetamol is generally well tolerated at recommended dose. Prolonged daily use can lead to serious side effects like kidney or liver damage[4,5],stomach bleeding[6], Hypersensitivity[7], (anaphylaxis[8,9] and fixed drug eruptions[10]) and Dermatological side effect like erythematous skin rashes associated with paracetamol have been reported but are rare. We have reported a case of paracetamol fixed drug eruptions.

## CASE REPORT

A 10 years old male patient was brought with a history of erythema rash that started on back and gradually became generalized all over the body, soles and mucosal surfaces over a period of since 1year recurrently. Rashes were well-circumscribed, 5-7 cm in size with a burning sensation without itching and blebs or pustules formation. These rashes were associated with intermittent moderate grade fever without chills and rigors. There was no history of similar complaints in the past. Hence, the provisional diagnosis of generalized erythematous rash of allergic origin was made. After admission, patient has given tablet paracetamol 500 mg three times a day, tablet prednisolone 10 mg twice a day and tablet chlorpheniramine maleate 25 mg twice a day. This oral treatment was also supplemented with intravenous fluids. The same day, late in the evening patient accidently noticed erythematous, macular, multiple lesions with size varying between 1 and 2 mm over the face and chest region, there was no itching, scaling or burning. Immediately, withdrawal of paracetamol was initiated suspecting it to be the causative agent. Thereafter, erythema associated with the lesions over the face started subsiding over next 2 days. On the 3rd

day after withdrawal of tablet paracetamol, erythema lesions over the over the total body completely evolved into hyperpigmented lesions in the phase of recovery. Paracetamol induced Generalized FDE is shown in ***FIGURE 01.*** The probability of Generalized FDE due to paracetamol cannot be ruled out after applying Naranjo's scale of causality assessment of adverse drug reactions with a score of 4. Laboratory investigations such as hemoglobin, complete blood count, and blood sugar level were found to be within normal limits. Rest of the treatment was continued and the initial symptoms improved over next 5 days. WHO ADR assessing scale karch and lasagna results were shown in ***TABLE 01.*** We also assessed the severity, predictability and preventability as a part of management through modified hart wig and Siegel severity scale, schomok and Thornton preventability scale.

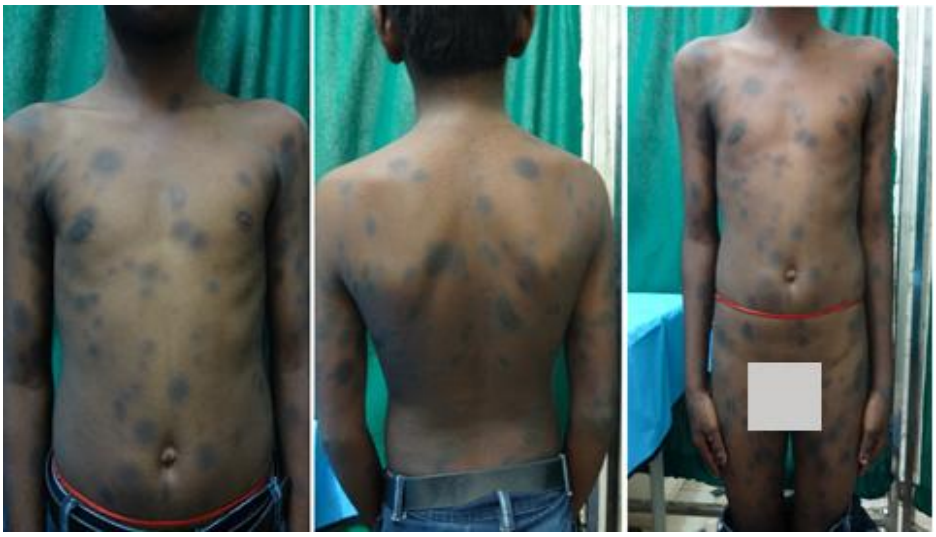

**Figure 1: Paracetamol induced Generalized FDE.**

**ADR Management:**

Generally, management of ADR includes withdrawal/suspension, dose reduction of suspected drug and administration of supportive therapy. Here in this case report, the suspected drug paracetamol was discontinued.

**ADR analysis:**

**Table 01: Causality assessment of suspected ADRs.**

| Suspected and Reaction | Naranjos Scale | WHO-Probability Scale | Karch and Lasagnas Scale |
|---|---|---|---|
| Paracetamol induced fixed drug eruptions | Possible | Probable | Probable |

**SEVERITY:** -Moderate level 4

**PREDICTABILITY:** -unpredictable

**PREVENTABILITY:** -Probably preventable

**DISCUSSION**

FDE is a cutaneous ADR which is commonly seen in children and adolescents. It is characterized by recurrent eruptions when the offending drug is re-administered. The hallmark of FDE is the recurrence in the same site on repeated administration of the offending drug [11]. In our case, the patient has erythematous rash that started on back and gradually became generalized all over the body sparing palms, soles surfaces over a period of 3 days had over the face same area, Rashes were well-circumscribed, 5-7 cm in size with a burning sensation without itching and blebs or pustules formation i.e., cutaneous surface. Paracetamol induced FDE is reported in the literature in <1.5% of all cases of FDE[12].This case is unusual because the affected patient was of the elder age group, whereas FDE affects children and adolescents. This could be attributed to the hyper-immune reaction which sensitized the individual to paracetamol. Besides, in this case, both cutaneous and some hyperpigmented manifestations. This case reflects a broad spectrum of events in FDE. Erythematous appearance is indicative of active phase of FDE[13], whereas the violet macular rash over the trunk and forearm imply recovery phase, which is characterized by hyperpigmented areas 14, the assessment of ADR is done by means of Naranjo's ADR scale. A score of >9 is indicative of definite ADR. A score of 1-4 is indicative of possible ADR[15]. Our patient had a score of 4, thus indicative of FDE. The present case shows a temporal relation between the drug paracetamol and the presence of FDE. A patch test would have been useful in

this case, but the patch test must be done on cases that are not on any immunosuppressants. In our case, patient was on tablets chlorpheniramine maleate, prednisolone from 1st day. Hence, a patch test would have yielded better results.

## CONCLUSION

Paracetamol is widely prescribed by physician as well as also a popular OTC drug. Physician must suspect if such reaction occurs during therapy involving paracetamol and should carefully evaluate drug-associated reaction. It is important that skin reactions are identified and documented in the patient record and patient should be explained properly not to use that drug so that their recurrence can be avoided in future.

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