



Overview on Adverse Drug Reaction Reported- A Case Report

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ABSTRACT:

Pharmacovigilance is an important step in the present era which is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm. Pharmacovigilance is defined as “the science relating to the collection, detection, understanding, assessment, monitoring and prevention of adverse effects with pharmaceutical products”. Adverse drug reaction (ADR) is defined as “the response to a drug which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of a physiological function”. This article focuses a case presentation reported for ADR; a 32-year-old female of pitta-kapha prakruthi resident of Mysuru, Karnataka visited the JSS Ayurveda Hospital, Mysuru for Greeva shula (neck pain) and associated skin issues. After the application of Six C ointment advised for skin ailments, patient developed skin rashes with blister formation over the dorsal surface of the right hand and the adverse reactions subsided after stopping the suspected drug. For this case report, Naranjo’s ADR Probability Scale assessment score was 3 and as such not any conclusive reports on Six C ointment of previous ADRs have been reported. There is a need to educate all the Medical Professionals and encourage them to analyze and report any adverse drug reactions or adverse effects that occur in a patient. This report highlights the need of implementation of Pharmacovigilance and additional researches to be carried out in the field of skin toxicity over Six C ointment.

1. Introduction

Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine related problem” [1]. Pharmacovigilance is all about identifying the hazards associated with pharmaceutical products and minimizing the risk of any harm that may come to patients. A drug or medicine is defined as, “any substance in a pharmaceutical product which is used to modify or explore physiological systems or pathological states for the benefit of the recipient”. Adverse drug reaction (ADR) is a part of Pharmacovigilance which is “a response to a drug which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of a physiological function” [2]. The

literature depicts the incidence of ADR to be 2.4-6.5% even in western countries, with only 6-10% of all ADRs being reported [3]. Meta-analysis done recently has suggested that ADR were between the fourth and sixth commonest cause of death [4]. Thus, the Pharmacovigilance program was initiated to collect, analyze and also to monitor ADRs to establish evidence based clinical safety profile for documentation from the Government of India, Ministry of AYUSH for ASU & H drugs.

Rashes are the most common cutaneous ADRs to any type of drugs and appear within first week of the drug therapy. Common causes of skin rashes are infective, drug, sensitive skin, and some of known cutaneous eruption by Penicillin, Phenytoin, Sulphonamide, Sulphonylurea, Thiazide, Anti-tuberculous drugs, Anti-malarial, Penicillamine, Ampicillin, Amoxicillin, etc [5].



There are references in Ayurvedic literature in which drug induced consequences are also given importance and to be monitored accordingly. This article discusses a case of skin rashes with blister formation in a patient on local application of Six C ointment.

Six C ointment is an Ayurvedic proprietary medicine contains Shuddha Gandhaka (Purified Sulphur), Shuddha Yashada (Purified Zinc) bhasma and Karanja (*Pongamia pinnata*) taila [6]. It contains drugs of mineral and herbal origin and is the drug of choice for most of the skin disorders like scabies, lesions, eczema and various other dermal infections.

2. Patient information (Case presentation)

A 32-year-old female of pitta-kapha prakruthi resident of Mysuru, Karnataka presented with the complaints of pain in the neck region since six months associated with morning stiffness and radiating pain to the right hand. She also presented with the history of patchy discoloration on the dorsal surface of right hand since two and a half months. Prior to presentation at JSS Ayurveda Hospital, Mysuru; the patient had been admitted to another facility for evaluation of her symptoms. Patient didn't get satisfactory relief so she approached at JSS Ayurveda Hospital, Mysuru on November 2020 with OPD number 139600 and diagnosed to have Vishwachi. She was not a K/C/O Diabetes nor Hypertension.

3. Clinical findings

At the time of reporting in the outpatient department, the patient was normal, conscious and well responding to the oral commands. Her weight recorded was 62 kg and blood pressure was 130/80 mmHg. She was medium in built and upon personal history she had poor appetite and often constipated bowels. She presented with the pain in the neck region associated with morning stiffness and also pain radiating to the right hand. Difficulty in the movement of the neck in daily routine works and pain aggravates while sleeping/resting. She also presented with patchy discoloration on the dorsal surface of right hand with no itching and burning sensation.

4. Diagnostic assessment

The patient falls under pitta-kapha prakruthi by nature and Nidana Panchaka (Five diagnostic principles) were

useful in identifying the disease with known Samprapthi of Ayurvedic classics. Dashavidha Pariksha (Tenfold examinations) provided sufficient details of the patient necessary to generate a treatment plan based on the diagnosis. Lab reports and MRI of Cervical spine also suggested the involvement of particular disc, nerve and proves the diagnosis.

5. Therapeutic intervention and timeline

On proper examination at JSSAMCH, she started with the following treatment includes Tab. Shallaki MR 1-0-1, Capro Arjit forte capsule 2-0-2 internally and Murivenna taila for local application in the neck region followed by Six C ointment locally on the dorsal surface of the right hand for patchy discoloration. Patient was advised to follow proper diet and regimen accordingly.

On fourth day application of Six C ointment locally she developed skin rashes followed by blister formation on dorsal surface of the right hand associated with burning sensation where required symptomatic treatment was given and the adverse reactions disappeared after stopping of the suspected drug.



Fig 1: Skin rashes and blister formation on the dorsal surface of the right hand

6. Follow-up and outcomes

Patient was monitored during the treatment and on the day of appearance of adverse reactions, the suspected drug was stopped and other medications were continued. After 20 days of follow up, the patient got relief from the neck pain and the patient was advice to follow proper pathya (diet). As such there was no adverse reactions noticed during the follow up period.

7. Discussion

To ensure the safety of drugs, to minimize the adverse effects and to provide maximum benefit to the patient,



Pharmacovigilance is of prime importance in this present era. Prevention of ADR plays a vital role in ensuring the patient safety, treatment plan which mitigates any possible adverse effects and identify the subgroup of patients who are likely to be susceptible to the adverse effect and modify the treatment choice accordingly [7]. So it is the prime duty to report all kinds of ADRs that can benefit the mankind.

We hereby presented a case of skin rashes with blister formation after the application of Six C ointment over dorsal surface of the right hand. There was a temporal relationship and positive de-challenge which points towards the association between the suspected formulation and the event. For this case report, Naranjo's ADR Probability Scale assessment score was 3 (Possible). As the reaction was appreciated at the site of application, it was evident that this reaction could be from the application of Six C ointment and not because of other oral medicaments. The drugs present in the Six C ointment are Shuddha Gandhaka, Shuddha Yashada bhasma and Karanja taila. It contains drugs of mineral and herbal origin and no other previous ADRs or any other conclusive reports on the same were being reported. It is important to identify whether this reaction was from the drugs used in Six C ointment or from any undesired method followed during the manufacturing of this particular batch product or from the default during the authentication of drugs collected initially or from any other impacts which has to be ruled out. So, it is very important to document the reaction and to send for further evaluation for the concerned centers which adds to the benefit of mankind.

Questions	Yes	No	Don't Know
1 Are there previous conclusive reports on the reactions?	+1	0	0
2 Did the ADR appear after the suspected drug was administered?	+2	-1	0
3 Did the ADR improve when the drug was discontinued a specific antagonist was administered?	+1	0	0
4 Did the adverse reaction reappear when the drug was re-administered?	+2	0	0
5 Are there alternative causes that could solely have caused the ADR?	-1	+2	0
6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic?	+1	0	0
7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
9 Was the adverse event confirmed by objective evidence?	0	0	0
Total Score	+3		

Score: > 9 = Certain; 5-8 = Probable; 1-4 = Possible; 0 = Unlikely

Fig 2: Naranjo's ADR Probability Scale Assessment

8. Conclusion

There is utmost importance for ADRs in clinical practice as concerned to the public health irrespective of any system of practice. So, there is a need to educate all

the Medical Professionals and encourage them to analyze and to report any adverse drug reactions or adverse effects that occur in a patient for proper documentation and further evaluation for the benefit of the mankind.

9. Patient perspective

Patient responded to the Consultations very positively and showed full cooperation throughout the treatment.

Informed consent

Written informed consent was obtained from the patient for the publication of this case report.

Author contribution

Literature search, Manuscript design, Manuscript preparation: Dr Rakshitha D

Concept, Manuscript review and Manuscript editing: Dr Jagadeesh G Mitti

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