



(CASE REPORT)



Overview of adverse drug reaction: A case report

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Abstract

Pharmacovigilance concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients and 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) comes under the umbrella of Pharmacovigilance 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 includes a case presentation reported for ADR; a 49 year old female patient visited the JSS Ayurveda Hospital, Mysuru on August 2023 and diagnosed to have Sandhivata. She was treated with medications internally and Kottamchukkadi churna for external application as lepa. On application of Kottamchukkadi churna, appearance of reddish rashes and itching over applied area of ankle joints of both legs was noticed. As such not any conclusive reports on Kottamchukkadi churna of previous ADRs have been reported. Currently there is utmost importance for ADR in clinical practice concerned to the public health is of prime importance; so there is a need to educate all the Medical Professionals and encourage them to analyse and report any adverse drug reaction or adverse effects that occur in a patient. This shall only be a step towards global acceptance of Ayurvedic drugs hence proper documentation and further evaluation is a need of the hour.

Keywords: Pharmacovigilance; Kottamchukkadi churna; Adverse Drug Reaction; Pharmaceutical product; Clinical practice

1. Introduction

Pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. WHO defines Pharmacovigilance as; it is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine related problem [1]. A drug or medicine is any substance in a pharmaceutical product which is used to modify or explore physiological systems or pathological states for the benefit of the recipient. The drug reaction or adverse drug reaction is the response to the medicine used in humans or animals [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]. Adverse drug reaction (ADR) comes under 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 [4]. Recent Meta-analysis has suggested that ADR were between the fourth and sixth commonest cause of death [5]. Thus the programme was initiated to collect, analyze and to establish evidence based clinical safety profile for documentation and to monitor ADRs from the Government of India, Ministry of AYUSH for ASU & H drugs.

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Kottamchukkadi churna is an Ayurvedic proprietary medicine contains *Saussurea lappa*, *Zingiber officinale*, *Acorus calamus*, *Moringa oleifera*, *Allium sativum*, *Hugonia mystax*, *Cedrus deodara*, *Brassica juncea* and *Alpinia galanga*. It contains drugs of herbal origin and useful in conditions like pain, inflammation, etc.

2. Case presentation

A 49 year old female patient presented with the complaints of pain in both the knee joints and ankle joints since one year associated with morning stiffness and pain. 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 August 2023 with OPD number 118724 and diagnosed to have Sandhivata. She was a K/C/O Rheumatoid arthritis and on medication since eight years. H/O previous allergic reaction to Kolakulathadi churna was noted. She got admitted in the hospital and on treatment following Gandharvahastadi taila and Dashamula kashaya 25 ml each for virechana, then started with Ajamodadi churna + Gokshura churna 1-1-1, Punarnavadi kashaya + Varunadi kashaya 1-0-1 internally and later Kottamchukkadi churna for local application as lepa followed by Tab. Grab 1-1-1 internally. She applied Kottamchukkadi churna as lepa using sufficient quantity of water over ankle joints on both legs and was wiped off after two hours but after wash, immediately she developed reddish rashes and itching over applied area of ankle joints of both legs. Then required symptomatic treatment was done for the reaction.



Figure 1 Appearance of rashes over ankle joint

3. Discussion

Pharmacovigilance is of prime importance in this present situation to ensure the safety of drugs so as to minimize the adverse effects and to provide maximum benefit to the patient and enrich Ayurveda. 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 [6]. So it is the prime duty to report ADRs that can benefit the mankind.

In this case report, the patient presented with the complaints of pain in both the knee joints and ankle joints associated with morning stiffness and pain. Following the treatment, on application of Kottamchukkadi churna over ankle joints on both legs, developed reddish rashes and itching over applied area. As the reaction was appreciated at the applied site of lepa it was evident that this reaction was purely from the application of Kottamchukkadi churna and not because of other oral medicaments. The drugs present in the Kottamchukkadi churna are of 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 Kottamchukkadi churna 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.

4. Conclusion

As famous saying says “Prevention is better than cure”, there is utmost importance for ADR in clinical practice as concerned to public health. It should be treated properly with care or it may become fatal. So there is a need to educate all the Medical professionals and encourage them to analyse and report any adverse drug reaction or adverse effects that occur in a patient. This shall only be a step towards global acceptance of Ayurvedic drugs hence proper documentation and further evaluation is a need of the hour.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

Required permission has been taken to publish this case report as an article from the concerned committee.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

References

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PHARMACOVIGILANCE OF AYURVEDA, SIDDHA, UNANI and HOMOEOPATHY (ASU & H) DRUGS

Reporting Form for Suspected Adverse Reactions

Note:

- ❖ Personal information of the consumers / patients / ADR reporter's will be kept confidential.
- ❖ All suspected reactions are to be reported with relevant details.

AYURVEDA	PPV C	JSS AYURVEDA MEDICAL COLLEGE & HOSPITAL, MYSURU, KARNATAKA	Code [021]
Ay-ITRA/021/001/2023			

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

Name: [Redacted]		Patient Record Number (PRN): 47950/118734	
Place of Birth: [Redacted]		IPD / OPD: [Redacted]	
Address: [Redacted]		Age: 49	
Village / Town: [Redacted]		Sex: Male / Female	
Post / Via: [Redacted]			
District / State: [Redacted]			
Diagnosis: Sandivata		Constitution and Temperament: Pittavata	

2. Description of the suspected Adverse Reactions

Date and time of initial observation	10/8/2023, 7pm
Description of reaction	Reddish rashes & itching over ankle joint & foot of both legs

3. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Others - Rheumatoid arthritis since 8 years

4. Addictions, if any? If yes, please specify: -

5. H/O previous allergies / Drug reactions, if any? If yes, please specify: Yes, allergic to Kolakulathadi churma

6. List of all ASU & H drugs used by the patient during the period of one month:

Name of the drug	Manufacturer / Batch no.	Dose	Form / Route of administration	Date of		Reason for use	Any unwanted occurrences
				Starting	Stopped / Continued		
Gandhava Hastedi DMK	SNA P0194	25ml + 25ml	Oxal	6/8/23	7/8/23	Sanku Vata	-
Ajagadadi	SNA N1354	1-1	Oxal	7/8/23	Continued		-
Gokshura churma	JSS Ayurveda Pharmacy Bicc03, Bicc03	1-1	Oxal	7/8/23	14/8/23	Kottamchukkadi Lepa churma	-
Punarnavadi	SNA N1693	1-0-1	Oxal	7/8/23	14/8/23		-
Kottamchukkadi Lepa churma	SNA P0194	-	E/A	10/8/23	Stopped	Kottamchukkadi Lepa churma	Reddish rashes & itching over joint of ankle of both legs
Tab. Grah	SNA N1354	1-1	Oxal	14/8/23	Continued		-


7. List of other drugs used by the patient during the period of one month:

Name of the drug	Manufacturer / Batch no.	Dose	Form / Route of administration	Date of		Reason for use	Any unwanted occurrences
				Starting	Stopped / Continued		
T. Saaz DS	-	1-0-1	Oxal			RA	-
T. Colter D	-	1-0-0	Oxal				-
T. Folvite 500mg	-	0-1-0	Oxal				-
T. Mext 10mg	-	4clays once by wak	Oxal				-

8. Details of the drug suspected to cause ADR:

- a. Name of the drug: Kottamchukkadi Churma
- b. Manufacturing date and Expiry date (if available): April 2023 to March 2025
- c. Remaining pack / label (if available):
- d. Consumed orally along with (water / milk / honey / or any other): E/A
- e. Whether any dietary precautions have been prescribed? If yes, please specify: -
- f. Whether the drug is consumed under medical supervision or used as self medication: Under medical supervision
- g. Any other relevant information associated with drug use: -

9. Management provided / taken for suspected adverse reaction:


Stopped Kottamchukkade choornam


10. Please indicate outcome of the suspected adverse reaction (tick appropriate)

Recovered: <input checked="" type="checkbox"/>	Not recovered: <input type="checkbox"/>	Unknown: <input type="checkbox"/>	Fatal: <input type="checkbox"/>	If Fatal Date of death:
Severe: Yes / No. Mild	Reaction abated after drug stopped or dose reduced: Yes			
	Reaction reappeared after re administration of drug: -			
Was the patient admitted to hospital? If yes, give name and address of hospital				
Yes, JSS Ayurveda Hospital, Mysuru				

11. Any abnormal findings of relevant laboratory investigations related to the episode done pre and post episode of ADR: -

12. Particulars of ADR Reporter:

Please tick: Patient / Attendant / Nurse / Doctor / Pharmacist / Health worker / Drug Manufacturer / Any others (please specify)
Name: Dr. P. Sudhakar Reddy
Address: Professor & HOD, Dept of Swasthavaritta, JSSAMCH, Mysuru
Telephone / E-mail: 

Signature of the reporter: 

Date: 18/8/2023

Please send the completed form to: The centre from where the form is received or

To The Coordinator,
 Intermediary Pharmacovigilance Centre for Ayurveda
 Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat - 361008, India
 Tele Fax : 0288 2676856 / 0288 2553936
 Website: <https://itra.ac.in/hospital-pharmacovigilance> , Email: ipvcjamnagar@gmail.com

The ADR Probability Scale (Program Coordinator has to fill this scale)

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	-1	0
5 Are there alternatives 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?	+1	0	0
Total Score	03		

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

The suspected Adverse Event is	Grade - 1 (Mild)	<input checked="" type="checkbox"/>
	Grade - 2 (Moderate)	<input type="checkbox"/>
	Grade - 3 (Severe)	<input type="checkbox"/>
	Grade - 4 (Threatening)	<input type="checkbox"/>
The suspected Adverse Event is	Serious	<input type="checkbox"/>
	Non-Serious	<input checked="" type="checkbox"/>
The suspected Adverse Event is due to	Physician	<input type="checkbox"/>
	Patient	<input type="checkbox"/>
	Drug	<input checked="" type="checkbox"/>
	Other Factors*	<input type="checkbox"/>

If possible, explain the other factors: -


 Signature
 Programme Coordinator