A combined administration of Aragvādādi kaṣāyam and Syrup Talekt induced skin rashes

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ABSTRACT

It is a common notion among people in India that herbal or Ayurvedic products are safe and do not produce any adverse effect. This is not true since Ayurveda has evaded many adverse effects which occur by combination of herbs. This axiom is potentiated by our report that occurs in the form of skin rashes. A 20-year-old South Indian female of Pittakapha prakṛti (constitution) after beginning therapy with Aragvādādi kaṣāyam (ARK) (poly-herbal formulation) and Syrup Talekt (poly-herbal patent formulation) for the treatment of recurrent incidence of abscess. Rash disappeared after stopping the suspected drug and treatment with Vībhītaki kaṣāyam (decoction of Terminilia bellarica) and Satadhauta ghṛtam. Possible and probable (score 6) were the causality according to WHO-Uppsala Monitoring Centre and Naranjo’s Adverse Drug Reaction Probability Scale and grouped under type-B reaction. To the best of our knowledge, this is the first case of skin rashes which seen after administration of ARK and Syrup Talekt. This report highlights the need of implementation of pharmacovigilance center in the hospital level and additional research in the field of skin toxicity of ARK and Syrup Talekt.

KEY WORDS: Abscess, Aragwadadi kashaya, Ayurveda, skin rashes, Talekt

BACKGROUND

Rashes are most common cutaneous adverse drug reactions (ADRs) to any type of drugs and appear within 1st week of the drug therapy.[1] Overall incidence of allergic drug reactions is variously reported as being between 2% and 25%.[2] Common causes of skin rashes are infective, drug, sensitive skin, and some of known cutaneous eruption by penicillin, phenytoin, sulfonamide, sulfonurea, thiazide, antituberculous drugs, antimalarials, penicillamine, ampicillin, amoxicillin, etc.[3] There are references in Ayurvedic literature on the way in which drug induced consequences. Such as manifestation of skin diseases on external administration of juice of Bhallātaka (Semecarpus anacardium),[4] by suppressing the urge of Chardi (vomiting).[5] Vamana mithyayoga (inadequate administration of emesis).[6] There are few recently published ADR reports on Ayurvedic drugs as Daśāṅga lepa (poly-herbal formulation) induced skin rashes[7] and thyroiditis, followed by ginger consumption.[8]

Aragvādādi (ARK) is well-known herbaceous decoction of Ayurveda used to treat various skin ailments.[9] The details of the formulation is listed in Table 1. Chardi (Emesis), Viṣavikāra (morbidity due to poisonous substance), Kaphavikāra (disorders due to vitiation of Kapha), Prameha (urinary disorders), Kaṇḍu (itching), Duṣṭavraṇa (nonhealing ulcer), Kuṣṭha (skin disease).

Syrup Talekt is another patent herbal medication of Himalaya Drug Company. Each 5 ml of syrup contains extracts of 18 mg of Aragvāda (Cassia fistula Linn.) and Haridrā (Curcuma longa Linn.), 16 mg of Nimba (Azadirachta indica A. Juss.) and Guducci (Tinospora cordifolia (Willd.) Miers ex Hook. f. & Thoms.) and 15.5 mg of Triphalā (combination of Terminalia chebula Retz., Terminalia bellirica (Gaertn) Roxb., Phyllanthus emblica Linn.), Vidaṅga (Emblica ribes Burm. f.), Bhringārāja (Eclipta alba (L.) Hassk.), Kirātātikā (Swertia chirayita Karsten) with methyl paraben sodium propyl and sodium benzoate being chemical preservatives. The company which manufactures this syrup claims this drug to be effective in the management of skin disorders.[10]

These two formulations are believed to be safe because of lack of reports suggesting dermatological manifestations. This report discusses a case of skin rash in a patient on oral administration of ARK and Syrup Talekt.
Preventive medication
The skin itching and rashes were gradually reduced 1 day after the discontinuation of Syrup Talekt and ARK and treatment with Vibhitaki kaśāyam (decoction of Terminalia bellirica) for washing followed by application of Satadhautaghṛta and oral medications of Vibhitaki kaśāyam (decoction of T. bellirica) 3 tsf before food and Candanāsava 3 tsf with water after food t.i.d. A complete cure was seen on 5th day of the above treatment. Patient’s written consent was taken for documentation and publication of this case.

DISCUSSION
We hereby presented a case of skin rash after consuming ARK and Syrup Talekt. There were a temporal relationship and positive dechallenge, which points toward the association between the suspected formulation and the event. No such reaction was noticed by any other patient on taking Syrup Talekt and ARK of the same batch. This points toward the susceptibility of the patient toward the reaction.

Causality assessment was done by WHO-Uppsala Monitoring Centre Causality Assessment Scale and Naranjo’s ADR Probability Scale the score of which are possible and probable (score 6) with Syrup Talekt and ARK administration respectively and severity was moderate. Dermatological reaction to ARK was not known, in fact the present formulation is known for its vast therapeutic applications on skin disorders hence, in present event cause is difficult to trace. The paraben is a well-known preservative used in kaśāyam and syrup, it is known to cause skin irritation and contact dermatitis in selective paraben allergy individuals. In present drug event, the involvement of preservative was ruled out as patient does not have a history of hypersensitivity to any of such preservatives. Hence, cause can be attributed to increased dose of administration of Aragvāda (Cassia fistula Linn.) Nimba (Azadirachta indica A. Juss.) and Guḍūcī (Tinospora cordifolia (Willd.)) which are common ingredients of both the formulations. Although, these drugs have not reported causing toxicity in increased dose of administration, but there is a remote possibility of administration of higher dose of these drugs might have caused the event. The firm conclusion can be drawn only after the re-challenging technique. In the present case, the re-challenging technique was not followed due to the patient discomfort and ethical issues.

Learning points
This may be a good example for unpredictable or

Table 1: List of ingredients of Aragvāḍā kaśāyam with its respective official part

| Ingredients | Part used |
|-------------|-----------|
| Aragvāḍa (Cassia fistula Linn.) | Bark |
| Indrayava (Holanthena antidysenterica Wall.) | Seeds |
| Pańala (Stereospermum suaveolens DC) | Root bark |
| Kākatikā (Swertia chirata (Roxb. ex Flem.) Karst.) | Whole plant |
| Nimba (Azadirachta indica A. Juss.) | Bark |
| Amṛtā (Tinospora cordifolia (Willd.) Miers ex Hook. f. & Thoms.) | Stem |
| Murū (Marsdenia tenacissima Wight and Am.) | Root |
| Kasakārī (Solanum xanthocarpum Schrad. and Wend.) | Root |
| Pata (Cissampelos pareira Linn.) | Root |
| Bhūnimba (Andrographis paniculata Wall. ex Nees.) | Whole plant |
| Sahacara (Bartetia priornit Linn.) | Root |
| Paŋala (Trichosanthes dioica Roxb.) | Root |
| Karārī (Pongamia pinnata Pierre.) | Root bark |
| Pāṭēkārāṅja (Holoptelea integrifolia Planch.) | Bark |
| Saptapāṛī (Alstonia scholaris R.Br.) | Bark |
| Citrāka (Plumbago zeylanica Linn.) | Root |
| Karavī (Elettaria cardamomum Maton.) | Fruit |
| Madanaphala (Randia dumetorum Poir.) | Fruit |
| Gorrī (Zizyphus jujuba Mill.) | Fruit |

CASE REPORT
A 20-year-old South Indian female of Pittakapha prakṛti (constitution), who had was a resident of Belgaum, Karnataka since birth, consulted us for abscess in her right thigh that had developed 3-month back together with fever and myalgia. Her history includes regular incidence of abscess once in 6-9 months. She was not known to have allergy to any food or drugs.

Intervention
A month back she was on Serratipeptidase with diclofenac sodium (15:200 mg) with a dose of 1-tablet b.i.d. for 7-day and previous day of the event patient was on ARK with dose of 3 tsf t.i.d. along with water. On the next day along with previous drug, Syrup Talekt was administered with a dose of 3 tsf with water before food in thrice daily.

Adverse drug event
On oral administration of ARK 3 tsf with water and Syrup Talekt 3 tsf with water, she has presented widespread skin rashes involving the abdomen, thighs, and upper arms [Figures 1 and 2]. No mucosal involvement was noted. The remainder of the physical examination was normal with no signs of conjunctivitis.
idiosyncratic reaction because it is very hard to predict cause and effect relation in modern pharmacology or Ayurvedic pharmacology as has been reported in the case of administration of Daśāṅga lepa induced skin rashes[7] so it may be grouped under type-B type of ADR.

Such unpredictable adverse reactions are not necessarily due to errors or negligence. It is difficult to predict host susceptibility to such response and thus it becomes very important to document, evaluate and report such reactions, so that its recurrence can be prevented in the future.

The detection of unknown and unexpected relationship between drug exposure and adverse events is one of the major challenges of pharmacovigilance. It is likely for an unexpected adverse reaction to go unnoticed until a very substantial number of patients have been adversely affected. Early detection of unknown and unexpected adverse reactions depends upon proper identification of signals and voluntary reporting system. Identifying and reporting such events plays an important role in preventing its recurrence.

Developing a practice of identifying ADR and its reporting will play an important role in a successful implementation of National Pharmacovigilance Program for Ayurveda Siddha and Unani (ASU) drugs.

This case has been reported to National Pharmacovigilance Centre for ASU drugs, Jamanagar, India on 08.01.2011.

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