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Sudden Generalized Weakness and Giddiness after administration of *Lekhana Basti* - An Unintended Drug Reaction (ADR)

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ABSTRACT

It is common belief in Indians that herbal drugs or Ayurveda medicines are always 100% safe and doesn't produce any of the adverse effects but which is not always true, well this is shown by our case report where the adverse effect were seen in the form of generalized weakness and giddiness. A South Indian Male patient of age 45 years who was resident of Belgaum for 10 years. Patient consulted us for the complaints of sudden weight gain with the associated complaints like heaviness of body, laziness etc. Giddiness and generalized weakness disappeared when dose of *Lekhanabasti* was reduced. Direct relation (score 6) were the causality according to Naranjo's Adverse Drug Reaction Probability Scale. This report highlights the importance of Preassessment and awareness towards the careful use of Ayurveda medicines like that of contemporary medications.

Key words: *Lekhana Basti*, *Unintended Drug Reaction*, *Adverse Drug Reaction*.

INTRODUCTION

Lekhan Basti is a type of *Niruhabasti* (rectal administration of colloid suspension mixture of herbal medicine) which is an amalgamation of different ayurvedic medicines which cause the *lekhan* depletion of the excessive *mēda* (fat) from the body. The drugs which are used in the preparation of *Lekhan Basti* are *Triphalā* decoction, Honey, *Gōmutra*, *Saindhava lavaṇa*, *Hiṅga*, *YavaKṣāra*, *Kāsīsa*, *Śīlājatu* which are *Mēdōhara* (reduce fat) by virtue of their

properties.^[1]

Dizziness is an impairment in spatial perception and stability. The term dizziness is imprecise: it can refer to vertigo, presyncope, disequilibrium, or a non-specific feeling such as giddiness or foolishness. One can induce dizziness by engaging in disorientating activities such as spinning.^[4] *Lekhan Basti* is a one of the commonly practiced *Niruhabasti* and any adverse reactions like giddiness and weakness are rare. This article discusses a case of sudden generalized weakness and giddiness manifestation in the patient suffering from obesity after the administration of the *Lekhana Basti*, this kind of reaction are uncommon in patient with *Santarpaṇajanyavyadhī* (disease caused due to over nourishment). Recurrence of such a type of reaction is avoidable by properly detecting, evaluating, understanding and reporting such an event.

Table 1: List of ingredients of *Lekhana Basti*.

SN	Drug Name	Scientific Name	Quantity
1.	<i>Mākṣika</i>	Honey	60
2.	<i>Saindhava lavaṇa</i>	Halite	10
3.	<i>Triphalāditaila</i>	Medicated oil	60

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4.	<i>Śatapuśpakalka</i>	<i>Pimpinella anisum</i>	40
5.	<i>Triphalākaṣāy</i>	Medicated decoction	200
6.	<i>YavaKṣāra</i>	<i>Hordeum vulgare</i>	1 pinch
7.	<i>Hirṅga</i>	<i>Ferulaassa-foetida</i>	1 pinch
8.	<i>Kāśisabasma</i>	Green vitriol	1 pinch
9.	<i>Gōmūtra</i>	Cows Urine	100

CASE REPORT

A South Indian Male patient of age 45 years who was resident of Belgaum for 10 years. Patient consulted us for the complaints of sudden weight gain with the associated complaints like heaviness of body, laziness. He got admitted for the Panchakarma management in KLE Ayurveda Hospital Shahapur, Belagavi, Karnataka, for the treatment of the same, after proper preassessment *basti* fitness was given.

Intervention

As the patient was of *Santarpaṇajanyavyadhī* i.e. (obesity) *Lekhana basti* was planned for the patient the ingredients of *lekhana basti* were as mentioned in table 1. From the day one the patient was administered with initially *udvarthana* (Powder massage) with *Kōlakulattādi Curṅga* followed by *Lekhana basti* in *Kala basti* pattern the *Lekhana Basti* was administered with the above-mentioned ingredients.

Adverse Drug Event

On the 3rd day i.e. 2nd *Lekhana Basti* patient developed sudden generalized weakness and giddiness immediately after the *Pratyāgamana* (elimination of the *basti*) of the *Lekhana Basti*.

Table 2: Treatment Protocol

SN	Day 01	Day 02	Day 03
1.	<i>Udvarthana</i>	<i>Lekhana Basti</i>	<i>Lekhana Basti</i>
2.	<i>Anuvāsana Basti</i>	<i>Anuvāsana Basti</i>	<i>Anuvāsana Basti</i>

Preventive Medication

History of the patient was reviewed for any of the any of the systemic illness and no systemic illness were found, Her *Prakṛti* (constitution) was assessed as *Pitta*

Kapha Prakṛti (*Pitta Kapha* constitution) by a standard questionnaire.^[2] The medicine which was administered to the patient in the form of *basti* was purchased from the GMP certified pharmacy. Immediately GRBS was performed and was found to be 110mg/dl, Blood pressure was 110/70mmHg and Pulse rate was 70 beats per minute. The patient was given the head low position, and oral glucose was administered, when the patient felt comfortable the patient asked to take the breakfast. On the 6th day the drug was challenged with the reduced dosage then no any adverse reactions were observed.

DISCUSSION

For most of the patient's vasovagal syncope commonly known as "common faint" such episodes are rare but self-limited and specific, transient triggers. However, for some patients, recurrent episodes are frequent for some drug intervention.^[3] Casualty assessment was done by Naranjo ADR probability scale and score revealed that the ADE are definitely caused by the *Lekhana Basti* it was 10, the causality was again assessed by the Casualty Assessment Scale which showed the ADE and the drug had the direct certain relation.

Such reports show the importance of the establishment of a pharmacovigilance cell in all Ayurvedic hospitals, so that information regarding ADR related to Ayurvedic formulations can be generated to study the ADR of Ayurvedic single herbs and formulations effectively. This case has been reported to the National Pharmacovigilance Centre Ayurveda Hospital, Siddha and Unani (ASU) drugs through Ayurveda Pharmacovigilance Centre present in KLE Ayurveda Hospital, on 17th October 2018

Learning Points

This may be a good example for unpredictable 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 *Lekhana Basti*.

Such unpredictable adverse reactions are not necessarily due to errors or negligence. It is difficult to

predict subject 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.

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 Regional Pharmacovigilance Centre for ASU drugs, KAHERs Shri B. M. Kankanawadi Ayurveda Mahavidyalaya, Shahapur, Belagavi, Karnataka, 590003.

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