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## SUDDEN GIDDINESS AND CHILLS AFTER ADMINISTRATION OF *KSHEERA BASTI* – AN UNINTENDED DRUG REACTION {ADR}

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### ABSTRACT

Drug safety is a very important aspect in medical practice and has evolved in years, drug safety of ASU drugs in particular has always been a debatable topic in modern pharmaceutical era. Apart from adopting all the safety measures it is also responsibility of physician to note and report the adverse drug reactions or events. Following is a case report where the adverse effect was seen in the form of giddiness and chills with profuse sweating. A Male patient of age 39 years diagnosed with clinical depression also presenting with generalized weakness was prescribed with *ksheera basti*. Giddiness and chills with profuse sweating immediately after elimination of *Ksheera basti* was observed, and the same disappeared after dose of 2cc of Avil was administered IM and orally glucose supplement was given. Direct relation (score 6) was the causality according to Naranjo's Adverse Drug Reaction Probability Scale. This report emphasizes the importance of Preassessment and awareness towards the careful use of medications and treatment protocol.

**Keywords:** *Ksheera Basti*, ADR, Giddiness Profuse sweating, Assessment, Allergic Reaction

**INTRODUCTION:**

An adverse drug reaction (ADR) is defined as a response to a medicinal product which is noxious and unintended. The pharmacovigilance system allows the identification and prevention of the risk associated with a use of the drug [1]. The major lexicons of Ayurveda have also described concerns about patient safety in the form of fitness, indications, contraindications for Panchakarma procedures, possible complications in the form of *Vyapats* (complications), and their management principles. *Basti chikitsa* (Trans rectal drug administration) is one among the *Panchakarma* procedure advocated in the *Vata pradhana* (predominance of *Vata*) diseases. Though *Basti* is considered as best for such diseases it also helps in the management of diseases originating by the virtue of *Pitta* and *Kapha dosha* [2]. *Ksheera Basti* (Trans rectal administration of emulsion of herbal medicines with major ingredient as milk.) is a type of *Niruha basti* which is an amalgamation of different herbal medicines [3]. 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]. *Ksheera Basti* is a one of the commonly practiced *Niruha basti* and any adverse reactions like giddiness and weakness are rare. *Ksheera basti* is type of *Mrudu Niruha Basti*. Which acts as a *Dosha Shamana* and *Brimhana* type of *Basti*. It is mainly indicated in *Asthi Pradoshaja* and *Majjavaha Sroto Vikaras* and where there is involvement of *Rakta* and *pitta*. It nourishes the *Asthi Dhatu* and there by pacifies its *Ashrayee Vata Dosha*. There are references of *Ksheera* being used as *Kashaya dravya* and also as *Avapa dravya* in *Basti kalpas* and these *Yogas* are considered as *Ksheera Basti*. This *basti* nourishes the *Asthi Dhatu* and there by pacifies its *Ashrayee Vata Dosha* [13]. This article discusses a case of sudden giddiness and chills manifestation in the patient after the administration of the *Ksheera Basti*, this kind of reaction are uncommon. Recurrence of such a type of reaction is avoidable by properly detecting, evaluating, understanding and reporting such an event.

**CASE REPORT:**

A 39-year-old male, known case of clinical depression associated with the generalized weakness visited KLE Ayurveda hospital. After the thorough examination of the patient and his clinical condition he was admitted in KLE Ayurveda Hospital

Shahapur Belagavi for the management of above said clinical condition.

#### **INTERVENTION:**

The plan of care was as follows: *Sarvanga Abhyanga* (whole body massage) with *Bala Ashwagandha Taila* followed by *Bashpa Sweda* (steam therapy), *Ksheera Basti and Anuvasana Basti* (medicated oil enema) with *Brahmi Ghrita* 50ml, *Shirodhaara* (pouring liquid on forehead with oscillatory movements) with *Ksheerabala taila* and *Shiro Talam* (application of the medicated paste on Bregma) with combination of medicines – *Sarpagandha Churna* (*Rauwolfia serpentina*), *Jatamamsi* (*Nardostachys jatamansi*) *churna*, *Brahmi Churna* (*Bacopa monnieri*), *Vacha churna* (*Acorus calamus* Linn) and *Asanabiltadi Taila*. The ingredients of *Ksheera Basti* were as mentioned in table no 01. Internal medication like *Brahmi Vati* 1BD, *Sarpagandha ghana vati* 1 OD, combination of *Avipattikara Churna*, *Godhanti basma* and *Pravala Bhasma* 1tsf TID and *Ashwagandharista* along with *Draksharista* 3tsf TID with warm water was advised.

#### **ADVERSE DRUG EVENT:**

On administration of 1<sup>st</sup> *Ksheera basti* patient developed sudden giddiness and chills with profuse sweating immediately after the *Pratyagamana* of *basti* (elimination of the *basti*).

#### **PREVENTION MEDICATIONS:**

Immediately after the event the patient was given the head low position. On examination Blood pressure was 110/78mmHg and Pulse rate was 78 beats per minute. GRBS was performed and was found to be 110mg/dl. After five minutes the giddiness reduced, however the chills continued hence a STAT dose of 2cc Injection Avil was administered intramuscularly. BP and pulse were continuously monitored and were found to be within normal limits. The chills ceased in next five minutes. The patient was given light food after he was comfortable.

**Assessment of ADR.** - The patient was reviewed for any history of the systemic illness and no significant findings were noted. The prakriti of the patient was assessed to be *Pitta Kaphaja Prkruti* (*Pitta* and *Kapha dosha* constitution) by a standard questionnaire [5]. The medicine used for preparation of *basti* were purchased from the GMP certified pharmacy. On the 2<sup>nd</sup> day the drug was rechallenged with the same dose and no any adverse reactions were observed. The condition was assessed with Naranjo's Adverse Drug Reaction Probability Scale<sup>6</sup> the total score attained was 6 which indicated Possible cause of ADR [7]. The reaction

1. Followed a temporal sequence after a drug.
2. Possibly followed a recognized pattern to the suspected drug.

3. Could be explained by characteristics of the patient's disease.

### DISCUSSION:

As in this patient reaction is not because of generalized weakness as there was Giddiness and chills with profuse sweating immediately after elimination of Ksheera basti, Probably it was due to drug as most of the patient's vasovagal syncope commonly known as "common faint", such episodes are rare but self-limited and specific, transient triggers [8]. However, for some patients, recurrent episodes are frequent for some drug intervention. Casualty assessment was done by Naranjo ADR probability scale and score revealed that the ADE are probable caused by the Ksheera basti it was 06, the causality was again assessed by the Casualty Assessment Scale which showed the ADE and the drug had the direct certain relation.

Milk is one of the usual common food allergens that triggers the immune response and shows symptoms like mild to moderate rashes, trouble in breathing and sudden loss of consciousness [9]. The lactose intolerance is something different from milk allergy. The lactose intolerance is inability of a person to digest the food and food products containing lactose [10]. The milk protein  $\beta$ -lactoglobulin being the most abundant present in the *Ksheera basti* might have

triggered the such reaction because it can manifest an allergic reaction through IgE mediated and non-IgE mediated pathway [11]. An IgE mediated allergy occurs when the antigen binds to the IgE antibody signaling the release of histamines [12] which are the inflammatory immune mediators resulting in an immediate allergic reaction which was observed in the case, that is the reason Injection Avil was administered and recovery from the chills was observed.

But there rises a question gain the milk present in the *basti* is processed with other herbal drugs and other ingredients of *basti* hence it's difficult to rule out the role of milk in creating the scenario.

ADR may occur with administration of any drug. Medicines from traditional systems of medicines are not exempted from this. One such good example is this case report of unpredictable reaction as it is difficult to predict the cause-and-effect relation in modern pharmacology or any branch of medical science as reported in case of administration of *Ksheera basti*.

Such uncertain adverse reactions are not necessarily caused because of negligence or errors. It is hard to predict patient's susceptibility to such events, therefore it is important to document, evaluate and report such an unintended drug reaction, so that its

reappearance of such events 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.

**Table 1: Ingredients of Ksheera basti**

S. No.	Drug Name	Scientific Name	Quantity
1.	<i>Makshika</i> (Honey)	Honey	80ml
2.	<i>Saindhava lavaṇa</i> (Rock salt)	Halite	5gm
3.	<i>Chandanabala lakshadi Taila</i> + <i>Kalyanaka Ghrita</i>	Medicated oil + Medicated Ghee	50ml
4.	<i>Kalka- Jatamamsi Churna</i> ( <i>Nardostachys jatamansi</i> fine powder) + <i>Kapikacchu Churna</i> ( <i>Mucuna prurita</i> ) + <i>Sarpagandha churna</i> ( <i>Rauvolfia serpentina</i> ) + <i>Vaca churna</i> ( <i>Acorus calamus</i> )	Medicated paste	40gm
5.	<i>Ksheerapaka</i> (decoction in milk) <i>Ksheera</i> (Milk) + <i>Sarpagandhā bharaḍa</i> (Coarse powder) + <i>Ashwagandha barad</i> ( <i>Withania somnifera</i> ) + <i>Guduchi</i> ( <i>Tinospora cordifolia</i> ) <i>bharaḍa</i> + <i>Musta</i> ( <i>Cyperus rotundus</i> ) <i>bharaḍa</i>	Medicated decoction prepared in Milk	200ml

**Table 2: Treatment Protocol**

S. No.	Treatment Plan
1.	<i>Ksheera Basti</i>
2.	<i>Sarvanga Abhyanga with Balashwagandha taila</i>
3.	<i>Shirodhaara with Ksheerabala taila</i>
4.	<i>Shirotalam with Sarpagandha churna</i> ( <i>Nardostachys jatamansi</i> ), <i>Jatamamsi churna</i> ( <i>Nardostachys jatamansi</i> ), <i>Brahmi Churna</i> ( <i>Bacopa monnieri</i> ), <i>Vacha churna</i> ( <i>Acorus calamus</i> Linn) and <i>Asanabīlwadi Taila</i>
5.	<i>Anuvāsana basti with brāhmī ghṛta</i>
6.	<i>Pranayama and Yoga</i>

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