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Case Report

ADVERSE DRUG REACTION FOLLOWING THE CONCURRENT USE OF ALCOHOL AND AYURVEDIC FORMULATION SAHACHARADI AVARTITA TAILA: A CASE REPORT

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ABSTRACT :

Background: Adverse drug reactions (ADRs) are uncommon but can cause significant complications in Ayurvedic therapies, especially when lifestyle factors are considered. *Sahacharadi Avartita Taila* used for managing musculoskeletal disorders was used for *snehapana* (internal oleation). **Case Report:** A 56-year-old male diagnosed with a condition similar to lumbar disc degeneration presented with radiating low back pain and numbness. He was admitted to the hospital on 12th October 2023 and treatment started by *Shamana Snehapana* with 10 drops of *Sahacharadi Avartita Taila* in milk daily. He developed acute inflammatory cellulitis on his face and required emergency hospital care on 4th day. **Results:** The medication was immediately stopped and a clinical review was done which revealed that the patient was consuming alcohol during the course of treatment, which was brought to our attention by a bystander. The patient had initially concealed his history of alcohol use. The development of cellulitis must have happened due to the intake of alcohol which interacted adversely with the *Snehapana*. Gradual recovery happened with administration of Intensive treatment. **Conclusion:** This case of Adverse Drug Reaction Following the intake of Alcohol and *Shamana Snehapana* emphasizes the importance of adhering to dietary and lifestyle guidelines as advised by the consultant during intake of *Snehapana*. The adverse reaction was likely due to alcohol consumption which was an important contraindication that the patient concealed and the seasonal influence of summer further aggravated the condition. This case highlights the need for thorough patient education regarding treatment protocols and contraindications. Ensuring compliance with classical guidelines and standard operative procedures is essential to prevent such adverse events and to safeguard patient outcomes.

KEYWORDS: Adverse Drug Reaction, Cellulitis, *Sahacharadi Avartita Taila*, Lumbar Disc Degeneration, Alcohol Consumption.

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1. INTRODUCTION

Gridhrasi is one among the *Nanatmaja vata vyadhi,* which is characterized by *Stambha* (stiffness), *Ruk* (pain), *Toda* (pricking pain), and *Spandana* (sensation), initially affecting *Sphik* (buttock) as well as posterior aspect of *kati* (waist) and then gradually radiates to posterior aspect of *uru* (thigh), *janu* (knee), *Jangha* (calf) and *Pada* (foot). [1] *Snehana* (oleation therapy) is regarded as a highly effective treatment in the management of *Gridhrasi* (Sciatica). It not only helps in pacifying the vitiated *Vata dosha* but also helps in restoring the degenerative changes associated with intervertebral disc pathology. [2] Due to its potent *Vata*-pacifying properties, *Taila* (oil) is regarded as the most beneficial among the *Chathush Sneha* (unctuous substances). [3] *Shamana Snehapana* with *Sahacharadi Avartita Taila* [4] 10 drops with milk was prescribed due to its *Ushna Virya* (hot potency) is considered as effective in treating *Adha Kaya Vatarogas* (lower body *Vata* disorders) and balancing *Vata* and *Kapha* Doshas. On the fourth day, the patient developed Cellulitis due to *mithya ahara* (inappropriate eating habits) that was done against the doctor's advice. An integrative strategy that combined elements of allopathic and Ayurvedic therapy was used to treat the illness.

For further analysis the suspected case of Adverse Drug Reaction (ADR) was promptly reported to the Peripheral Pharmacovigilance Center. This case report offers valuable insights that could aid in establishing standardized protocols for managing similar adverse reactions in routine clinical practice, while also highlighting the significance of adhering to *Parihara Vishayas* during such complex procedures. Moreover, it aimed to strengthen the culture of reporting ADR within Ayurvedic practices, in order to enhance patient safety and the overall quality of care.

2. METHODOLOGY:

Patient Information

A 56-year-old male presented to the outpatient department with a history of low back pain radiating to both lower limbs, associated with numbness over the dorsal aspect of the feet since 2 months. The pain was gradual in onset, continuous in nature, aggravated by physical exertion and prolonged walking, and was relieved by rest. The patient sought consultation for more effective management of these symptoms. A thorough clinical examination was done, followed by *Shamana Snehapana* with *Sahacharadi Avartita Taila* 10 drops with milk was initiated till the patient achieved *Roga shamana* (reduction of symptoms). However, on the fourth day the *Snehapana* was discontinued as the patient developed pain and swelling associated with crust formation in the face.

During the initial case assessment the patient did not disclose his history of alcohol consumption. However, as part of the retrospective evaluation in order to identify potential causes for the adverse drug reaction, both the patient and his bystander were interviewed separately regarding any deviations from the prescribed regimen, including unusual dietary or substance intake. During this inquiry, the bystander revealed that the patient had consumed alcohol during the course of treatment.

Clinical Findings

a. During the Initial Assessment

Examination of Lumbar Spine revealed tenderness and restricted range of movement. The Straight Leg Raise (SLR) test was bilaterally positive. Neurological examination showed involvement of the L4-L5 and L5-S1 dermatomes along with mild paresthesia in both lower extremities. Reflexes were found to be normal. At the time of presentation there were no systemic symptoms or indications of infection

b. Post-ADR Clinical Presentation

Cutaneous examination indicated crust formation associated with mild exudation of blood and serous fluid over the left cheek, extending across the nose and periorbital region. These changes were accompanied by localized pain, swelling, and an itching sensation, which suggested an acute inflammatory skin response.

Timeline:

Table 1: The timeline of the events for the presented case is detailed.

Date	Event	Details
12th October 2023	Admission to hospital	Patient admitted for the Ayurvedic management of *Vataja Gridhrasi* (sciatica).
12th October 2023	Initiation of treatment	*Shamana Snehapana* was started with *Sahacharadi Avartita Taila* administered in milk.
16th October 2023	Adverse reaction observed	The patient developed pain and swelling associated with crust formation on the face, suggestive of an adverse drug reaction (ADR).
16th October 2023	*Snehapana* was discontinue	On examination clinical signs indicated an adverse drug reaction, *Shamana Snehapana* was promptly discontinued, and emergency management was initiated using an integrative approach combining Ayurvedic and allopathic interventions to address the adverse event effectively.
28th October 2023	Discharge from hospital	Patient discharged under medical advice with follow-up medications prescribed for continued outpatient care.
Post-discharge	Pharmacovigilance reporting	The adverse drug reaction was reported to the Peripheral Pharmacovigilance Centre.

Diagnostic Assessment

- **Laboratory Tests**: test reports found normal.
- **Radiographic Findings**: MRI lumbar spine: L4-L5 and L5-S1 shown signs of disc degeneration.

Therapeutic Intervention

The plan of care advised for the management of *Vataja Gridhrasi* are *Shamana Snehapana* followed by *virechana* and *Erandamoola Niruha Basti*. However, on the fourth day of *Sahacharadi Avartita Taila Snehapana*, the patient developed facial cellulitis as shown in Fig 1, leading to the immediate discontinuation of the *Snehapana*. Patient was referred to a higher center for Standard cellulitis management and was initiated on broad-spectrum antibiotics to control the infection and analgesics for pain relief. Over the following five days, there was a gradual reduction in facial erythema and swelling. After this improvement, Ayurvedic treatment was resumed and has been detailed in Table 2.

Table 2 – Therapeutic interventions and timeline

Date	Complaints	Intervention	Remarks
12/10/23 to 16/10/23	Low back pain radiating to both lower limbs, accompanied by numbness on the dorsal aspect of the feet	*Shamana Snehapana* with *Sahacharadi Avartita Taila* in milk	Reduction of pain
16/10/23	Pain and swelling in the face associated with crust formation	Broad spectrum antibiotics for 5 days	Diagnosed for cellulitis
21/10/23 to 28/10/23	Pain and swelling in the face	*Parisheka* using *Triphala* and *Yashtimadhu Kashaya.* Local application of *Jatyadi Ghrita.* Internal Medicines 1. *Triphala Guggulu* one tablet thrice a day, after food. 2. *Avipatti Choorna* (15g with honey in the morning)	The severity of pain and swelling got reduced gradually.

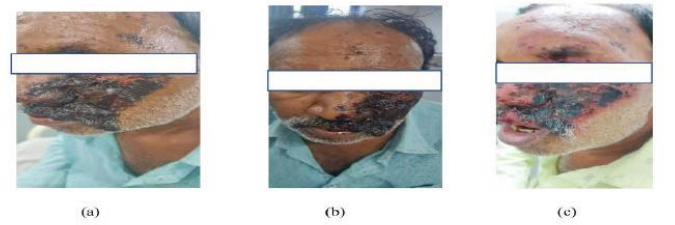

Fig. 1 -
(a) Patient presented with inflammatory cellulitis and crusting over the face: side view (16/10/23).
(b) Patient presented with inflammatory cellulitis and crusting over the face: front view (16/10/23).
(c) Symptoms showed improvement within 5 days following an integrative patient care. (20/10/23)

Fig. 1 – Patient's presentation pre- and post-intervention.

Follow Up and Outcome

The swelling and redness got reduced after five days of treatment for ADR. The healing process was evident in the lesion. The patient was discharged on October 28, 2023, when the lesions dried and the chances of further infection were ruled out. Follow-up medications were given, which are mentioned in Table 2, and the next review is scheduled for November 12, 2023.

Table 2 - Follow-up medications

Date	Intervention	Dose	Duration
28/10/23	1. *Triphala Guggulu* 2. *Jatyadi ghrita*	One tablet thrice a day, After food. External application over the skin lesion.	15 days

3. DISCUSSION

Visarpa, as the name suggests, the lesions are characterised by their fast-spreading nature, and the slow evolving nature differentiates *kushta* from *visarpa* if it is taken for comparison. [5] Coming to the *Nidanas* (causative factors) for *Visarpa*, consumption of *Tila Taila* (sesame oil) and *Madya* (alcohol) plays a role. [6]

The case of *Gridrasi* was treated with *Sahacharadi taila* for *shamana snehapana*, which is a tila taila-based formulation. The *Ushna Veerya* (hot potency) and *Teekshna Guna* (sharp quality) of *Tila Taila* aggravate *Pitta,* provoking *Rakta Dushti* (vitiation of blood), causing *visarpa*. [7]

The patient has not revealed that he had consumed alcohol during the treatment, which is one of the possible reasons for this ADR. *Madya* (alcohol), due to its *Ushna, Teekshna, and Vyavayi Guna,* adds to the contributing factors for *visarpa.* This article highlights the importance of 10-fold *pareekshya bhavas* (patent assessment) before framing a treatment protocol. According to classical texts, *Sneha* should be administered at night during *Greeshma Ritu*; however, in this case, it was given in the daytime. Therefore, this can be considered as a *Mithya prayogajanya Snehapana Vyapad* (regimen-noncompliance-induced adverse reaction) which is a resultant of both *Aturakritha* (patient-induced complication) and the *Vaidyakritha* (iatrogenic complication). [8] The cumulative effects of *taila, Madya,* and *Greeshma ritu* caused the *pitta* aggravation, leading to the manifestation of *Agni visarpa,* which got its nomenclature after it resembled the burning charcoal. [9, 10] The patient expressed considerable anxiety due to the involvement of the face, and he was worried that the disfigurement would be permanent, which could lead to social stigma and potentially disrupt personal and social life. To provide immediate relief and reassurance, we initiated allopathic treatment for acute management. Once the red flag signs were under control, Ayurvedic therapy was introduced, which gave a noticeable and steady improvement.

Management was guided by Ayurvedic principles targeting systemic inflammation and local wound healing. *Triphala Guggulu,* [11] when administered internally, has the *Shotha-hara* (anti-inflammatory) effect, and for *Pitta Shamana Avipattikara Choorna* [12] is given, which together acts at the *Visarpa Samprapti* (pathogenesis). *Triphala* and *Yashtimadhu Kashaya Seka* help to do *Vrana Shodhana,* and external application of *Jatyadi Taila* [13] does the *Vrana Ropana*. The combined approach taken here helped in the effective management of ADR.

4. CONCLUSION

This article focuses on the strict approach, especially in patient education, diet and lifestyle advice, and adherence to the therapeutic guidelines to prevent the occurrence of ADR. This case report highlights the importance of exercising a strict vigilance system in the observation of physicians, especially in patients with alcohol or other substance use dependency. Also, the timely adoption of an effective protocol for the management of ADR and the discontinuation of the medication were crucial.

Declaration of Patient Consent – The authors confirm that they have acquired a patient consent form, in which the patient or caregiver has granted permission for the publication of the case, including accompanying images and other clinical details, in the journal. The patient or caregiver acknowledges that their name and initials will not be disclosed, and sincere attempts will be undertaken to safeguard their identity. However, complete anonymity cannot be assured.

Patient perspective: as dated on 28th October 2023

"I had taken Ayurvedic treatment for my back pain on 12th October 2023, and because of my misbehavior, the treatment got interrupted, and I suffered from skin manifestations on my face. All these events happened after the intake of alcohol, which I agree at this point of time is purely because of disobeying the instructions explained by the physician. When things got out of control, the physicians had intervened promptly with utmost care and explained things well. The integrative approach taken in my case has helped

with my fast recovery, and the amount of pain that was experienced initially has improved significantly. This sequence of events, which I had passed through, cemented my belief in Ayurveda."

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