JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

ADVERSE DRUG REACTION INDUCED BY GANDHA TAILA: A CASE REPORT

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Abstract*: Gandha Taila* is a classical Ayurvedic polyherbal formulation indicated in the diseases of bones including arthritis, fracture and osteoporosis. Although generally considered safe, adverse drug reactions (ADRs) may occasionally occur. A 31-year-old female developed generalized pruritus with erythematous papular eruptions following administration of *Gandha Taila* in combination with *Lakshadi Guggulu*. The symptoms resolved completely after discontinuation of the medicines and symptomatic management. Further, on re-introduction of *Gandha Taila* at a reduced dose, no reccurence of ADR was observed. This case highlights a rare, dose-related cutaneous ADR, associated with *Gandha Taila.* The report underscores the importance of pharmacovigilance in Ayurvedic practice, which aims at vigilant monitoring and transparent reporting of adverse events.

Keywords: *Gandha Taila, Lakshadi Guggulu,* Adverse drug reactions, Pruritus, Pharmacovigilance

I. INTRODUCTION

"There is not even a single substance in the world that cannot be used as a medicine" is the fundamental principle of Ayurvedic practice [1-2]. Based on this very principle, three types of substances namely *Jangama* (Animal products), *Sthavara* (Herbal drugs) and *Parthiva* (Minerals) are used in various formulations [3-4]. Application of these either individually or in combinations leads to various permutations of therapeutic compounding. These raw materials can be converted into a suitable dosage form through selected pharmaceutical processing techniques which aim at preparation of medicines suitable for internal administration [5]. They are administered according to the condition and convenience of the patient. It is mentioned that different dosage forms can be made by the *Yukti* (thoughtful applications) of the physician involving principle of *Samyoga* or *Vibhaga*. The potency of a product can be increased or decreased by the same principle [6]. However, it is important to note that the ideal medicine is the one which shows desired results in minimum dosage, act fast, easily metabolized and importantly should not cause any harm to the body [7-8].

The formulations in Ayurveda are usually thought by patients and general public to be harmless, and the manufacturers take advantage of this belief and advertise their products [9-10]. But it is against to the principles, as ample references on '*Apakva oushadha sevanajanya vikara' or 'Vyapath'* due to improper usage of formulations and therapies have been illustrated in Ayurvedic literatures [11-22]. In view of this, Pharmacovigilance has come to forefront to document the adverse drug reactions or adverse events of Ayurvedic therapies. Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. Given the increasing challenges and concerns surrounding Ayurveda, it is essential to integrate pharmacovigilance into practice to ensure safety and address health risks effectively [23].

Ayurveda advocates number of classical and proprietary formulations in the management of *Vataja* disorders, particularly conditions involving bone and joint tissues. *Gandha Taila* is one such classical formulation possessing *Vatahara, Shothahara,* and *Asthi-dhatu poshaka* properties. This is gingelly oil-based preparation, wherein milk, *Yashtimadhu, Manjishta, Sariva, Ela, Jivaka, Tagara* and such other 20 drugs are added as ingredients [24]. In this article, an attempt is made to document an adverse drug reaction reported by a patient after taking *Gandha Taila.*

II. AIM

To document and analyze a dose-related adverse drug reaction associated with Gandha Taila.

III. CASE REPORT

A 31-year-old female, weighing 48 kg, presented with low back pain following a road traffic accident. She was diagnosed with *Abhighataja Katishoola*. She had a history of osteopenia and no known drug allergies. *Gandha Taila* and *Lakshadi Guggulu* were prescribed for internal administration, the details are given in Table 1. On the fourth day of treatment, the physician advised an increase in the dose of *Gandha Taila*. Following consumption, the patient developed acute-onset generalized pruritus

accompanied by erythematous papular eruptions over both upper and lower limbs. (Figure 1). No mucosal or systemic involvement was observed. The patient reported sleep disturbance secondary to pruritus.

Table 1: Timeline of drug administration and adverse drug reaction

Day	Clinical Event
Day 0 (Day 1& 2)	Gandha Taila (4 drops with milk, after food BD) Lakshadi Guggulu (2 tablets with lukewarm water, after food BD)
Day 3	Gandha Taila (4 drops with milk, after food OD)
Day 4	Gandha Taila (6 drops with milk, after food OD) Onset of generalized pruritus and erythematous papular rashes
Day 5	Dechallenge – both medicines stopped
Day 8	Complete resolution of symptoms
Day 9	Rechallenge - Gandha Taila (4 drops with milk, after food OD) Lakshadi Guggulu (2 tablets with lukewarm water, after food) No recurrence of pruritis or rash was observed

IV. Discussion

Gandha Taila is a classical Ayurvedic medicated oil to promote bone mass, enhance joint strength, and support the healing of fractures and ligament injuries. In addition to its indication in *Asthi-bhagna* (fractures), it is also considered beneficial for the muscles, ligaments and tendons surrounding the bones. It is believed to nourish *Asthi Dhatu* while balancing *Vata* and *Pitta dosha*. Its therapeutic actions are attributed to anti-inflammatory, analgesic, and tissue-repairing properties. It is usually administered orally in the form of drops, mixed with warm milk. It is pertinent to note that there is no specific dose mentioned for *Gandha Taila* in the classical literatures. So it is usually given in a dose of 1 ml, based on *Anubhuta pramana* (empirical evidence) as prescribed by traditional practitioners. Earlier studies on clinical evaluation on efficacy of *Gandha Taila* have shown significant therapeutic benefits in the management of osteoporosis and fracture [25-26].

Lakshadi Guggulu is a polyherbal formulation renowned for accelerating fracture healing, improving bone mineral density, and relieving musculoskeletal pain. Composed of *Laksha, Shuddha Guggulu, Arjuna, Ashwagandha,* and *Nagabala,* it supports bone mineralization, reduces inflammation, and strengthens the muscles and joints. Commonly prescribed in conditions such as fractures, osteopenia, osteoporosis, and arthritis, it is generally administered after meals with warm water or milk under medical supervision. Earlier studies on clinical evaluation on efficacy of *Lakshadi Guggulu* have shown significant results in the management of osteo arthritis of knee, fracture, osteoporosis and exhibiting anti-arthritic effects [27-30].

Ayurvedic practitioners often prescribe *Lakshadi Guggulu* and *Gandha Taila* together to provide comprehensive effect on fracture, bony pain, osteoarthritis or such other diseases of bone. The key ingredients in both formulations provide nutritional support to the bones while simultaneously enhancing structural strength. They work synergistically to fasten the healing process in bone injuries and provide anti-inflammatory and analgesic effects. Further, by virtue of pharmaco-therapeutic properties as per Ayurvedic principles, they support the regeneration of new bone tissue and strengthen ligaments. A significant improvement in knee joint ligament injury was reported by combination of *Gandha Taila* and *Lakshadi Guggulu* [31].

In the present case, pruritus with erythematous papular eruptions were seen in the patient when the dose of *Gandha Taila* was increased. At lower doses, up to the fourth day of treatment, no adverse reactions were observed. Following discontinuation of the medicine, the symptoms subsided. After a three-day gap, the therapy was restarted at a reduced dose, and no recurrence occurred. This case thus represents a typical example of a dose-related cutaneous adverse drug reaction associated with *Gandha Taila*. Although the formulation is predominantly *Vatahara*, the presence of *Krishna Tila*, recognized for its *Pitta-vardhaka* property, together with patient-specific factors such as a *Pitta-pradhana* constitution and dose escalation, may have contributed to the reaction. The causality assessment (Table 2) of the reported adverse event was performed using the WHO–UMC scale, and the reaction was classified as "Possible." This classification is justified as a reasonable relationship as the onset of the adverse drug reaction was evidently seen after dose of *Gandha Taila* was increased. However, the presence of potential confounding factors such as *prakruti, ahara, vihara,* and the absence of definitive pharmacological evidence are the constraints to generalize this finding with certainty. The positive dechallenge, evidenced by the resolution of symptoms following withdrawal of the intervention, supports a plausible association. Further, the negative rechallenge, wherein the consumption of medicine in a reduced dose did not reproduce the adverse event. This observation reinforces the "Possible" categorization rather than "Probable" or "Certain." In terms of clinical impact, the adverse event was assessed as mild in severity and non-serious, as it did not result in hospitalization, persistent disability, or any life-threatening condition.

Adverse drug reactions are broadly classified into two types. Type A reactions, also referred to as 'Augmented reactions', are dose-dependent and predictable based on the pharmacological properties of the drug. In contrast, Type B reactions, commonly termed 'Bizarre reactions', are idiosyncratic and not predictable from the drug's pharmacology [32]. In the present case, the absence of recurrence upon re-challenge with a reduced dose strongly supports a dose-dependent mechanism (Type A) rather than an idiosyncratic response (Type B). This highlights the importance of careful dose titration and monitoring in clinical practice, especially when standardized dosing guidelines are not available.

Table 2: Causality and severity assessment

Parameter	Assessment
Causality (WHO–UMC)	Possible
Severity	Mild
Seriousness	Non-serious
Dechallenge	Positive
Rechallenge	Negative

Fig 1: Erythematous papular eruptions over the extremities after administration of *Gandha Taila*

V. CONCLUSION

This case report highlights a rare, mild, reversible, dose dependant ADR induced by *Gandha Taila*. The formulation produced pruritus with erythematous papular eruptions when the dose was increased. This case reiterates the importance of careful monitoring of both dose and duration in Ayurvedic therapies. The case emphasizes the need for an individualized approach rather than a generalized one. Prompt identification, documentation and reporting of adverse events are essential for ensuring the safety of Ayurvedic practice. Furthermore, systematic ADR reporting contributes significantly to strengthening the pharmacovigilance framework and advancing the integration of traditional medicine into evidence-based healthcare.

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