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Case Study

Adverse reaction of *Parasika Yavani* (*Hyoscyamus niger* Linn): Two case study reports

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Abstract

Adverse drug reaction (ADR) is an unpleasant reaction related to the use of medicine at its therapeutic dose. Ayurveda is well aware of such adverse reactions. *Parasika Yavani* (*Hyoscyamus niger* Linn.) is an Ayurvedic drug effectively used in many psychological disorders, if not used judiciously it causes adverse reactions. In present study two cases of ADR on the usage of *Parasika Yavani* are reported. *Churna* in capsule form given in different dosage forms (500 mg once a day, 250 mg twice a day, 250 mg once a day) in *Chittodwega* (generalised anxiety disorder). 500mg capsule was given to many patients in the study, but no adverse reactions were noticed except in above given two cases. So, in these two cases, the dose was tapered down to 250 mg twice a day, and then to 250 mg once a day to avert the adverse reactions and to fix the therapeutic dose in such individuals (250 mg once a day). On analysis, these two individuals were found to be of *Pitta Prakriti*. *Parasika Yavani* is found to increase *Pitta* and triggers the establishment of ADRs. So, while administering therapeutic dosage, a physician should be vigilant. In the current study, it is observed that 500 mg of *Parasika Yavani* powder in *Pitta Prakriti* individuals triggered ADRs while 250 mg once a day was safe. It was also observed that *Kapha* and *Vata Prakriti*, patients did not develop any adverse reactions.

Key words: Adverse drug reaction, Ayurvedic drug, *Parasika Yavani*, *Pitta Prakriti*, therapeutic dose

Introduction

Ayurveda offers a system of natural healing that is very complete both in terms of its treatment and also in its understanding of the human being. It offers a vision of healing for curing disease, for preventive health, and ultimately for spiritual liberation.[1] Since ages, Ayurveda is being practiced in India. Now in this era of globalization, certain concerns are being raised with regards to the safety of plants or plant based products. Adverse reactions of many Ayurvedic medicines are yet to be reported. Ayurveda has categorized toxic plants separately and for their use, special processing is essential.[2] If not processed properly and not used judiciously, these drugs may prove to be fatal. It is the need of the hour to report all such adverse drug reactions (ADRs) associated with administration of Ayurvedic drugs.

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An ADR can be termed as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration, and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product."[3] ADRs are classified into six types: Dose-related (augmented), dose-related (bizarre), dose-related and time-related (chronic), time-related (delayed), withdrawal (end of use), and failure of therapy (failure). Timing, the pattern of illness, the results of investigations, and rechallenge can help attribute causality to a suspected ADR. Management includes withdrawal of the drug, if possible and specific treatment of its effect.[3] Few such adverse

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reactions are observed while administering the single drug *Parasika Yavani* (*Hyoscyamus niger* Linn.).

Parasika Yavani commonly known as Henbane is considered as a *Madaka Dravya* (narcotic) by Bhavaprakasa.[4] It is useful in conditions such as *Unmada* (psychological disorders), *Anidra* (insomnia), etc.[5] In the present study, *Parasika Yavani Beeja Churna* (seed powder) was given in the treatment of *Chittodwega* (anxiety).

Case Reports

Case 1

A 30-year-old male patient, a normotensive and nondiabetic of *Pitta* predominance was diagnosed as a case of generalized anxiety disorder. The patient was administered with 500 mg *Parasika Yavani* seed powder once daily in June 2013 as a part of study conducted at IPGT and RA, Jamnagar. After two days, the patient presented with severe headache, blurred vision, burning sensation in eyes, and hot flushes. Patient was asked to withdraw the medicine for two days. By the second day, the symptoms were found to be relieved. The medicine was restarted on the third day and similar symptoms were again manifested. Medicine was again withdrawn and after 1-week 250 mg of the same medicine was given twice daily. Patient reported mild headache on taking the medicines, so it was discontinued. After two days, 250 mg once daily was given, and the patient was found to be comfortable with the dose. The patient continued the medicine for the next 28 days without developing any ADR.

Case 2

A 37-year-old male patient of *Pitta Prakruti* was treated for generalized anxiety disorder with 500 mg of *Parasika Yavani* seed powder once daily in as a part of study conducted at IPGT and RA, Jamnagar. On second day, the patient presented with severe headache, blurred vision, and pain in the eyes. Medicine was discontinued. Three days later, the patient was given 250 mg of same powder twice daily. Patient reported again similar symptoms on the third day. Medicine was stopped, and 250 mg once daily was started after a week. The patient did not complain any adverse reactions on this dose and continued it for a month.

Discussion

Parasika Yavani seeds are *Katu* (bitter), acrid, *Madaka* (narcotic), *Vedanasthapaka* (analgesic), *Krimighna* (antihelminthic), *Sulaprashamana* (antispasmodic), *Nidrajanaka* (induces sleep), anti-inflammatory, and expectorant.[6] They are useful in *Unmada* (psychological disorders), *Anidra* (insomnia), *Pralapa* (restlessness), odontalgia, bleeding gums, dental caries, orchitis, rheumatoid arthritis, dyspepsia, worm infestation, cardiac debility, flatulence, colic, asthma, bronchitis, neuritis, fever, meningitis, amenorrhea, urinary tract infection, and irritability.[5,7] It contains tropane alkaloids called, hyoscine (scopolamine), hyoscyamine (L-atropine), and atropine (DL-hyoscyamine).[6] In higher dose, it causes dry mouth, thirst, difficulty in swallowing, and speaking, warm flushed skin, dilated pupils, blurred vision, and photophobia, vomiting, urinary retention, tachycardia, pyrexia, drowsiness, slurred speech, hyper-reflexia, auditory, visual, or tactile hallucinations, confusion, disorientation, delirium, agitation, and combative behavior. In severe cases, there may be hypertension, coma, and convulsions.[6,8]

The dosage of seed powder given in different Ayurvedic and modern texts vary from 125 mg to 3 g.[5] In above reported cases, the dosage given was within the advised therapeutic dosage limit. 500mg capsule were given to many patients, but no adverse reactions were noticed except in above given two cases. So, the dose was tapered down to avert the adverse reactions and to fix the therapeutic dose. The reactions observed in the current study can be categorized under type A/dose-related ADR. On analysis, these two individuals were found to be of *Pitta Prakriti*. *Parasika Yavani* is found to increase *Pitta*.[6] Possibly, the drug aggravates *Pitta* in such individuals and triggers the establishment of ADRs. It was also observed in the same research study that the patients belonging to *Kapha* and *Vata Prakriti* did not develop any adverse reactions.

The principles of Ayurvedic treatment were established on the basis of "*Purusham Purusham Veekshya*" that is, each patient is unique, and different.[9] Ancient texts were very well aware of the toxicity and provided guidelines to avoid such manifestations. *Prakriti* of the patient plays a very important role in the drug administration, and metabolism. So while administering therapeutic dosage, physician should be vigilant.

Conclusion

In the current study, it is observed that 500 mg of *Parasika Yavani* powder in *Pitta Prakriti* individuals triggered ADRs. It was also observed that *Kapha* and *Vata Prakriti* patients did not develop any adverse reactions. And as per observations from study 250 mg once daily is found to be ideal in *Pitta Prakriti*.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

दो रूग्णों में पारसिक यवानी के प्रतिकूल प्रभाव का अध्ययन

अपर्णा के., अभिषेक जे. जोशी, महेश व्यास

पारसिक यवानी आयुर्वेदिक औषधि है जिसका कई मानसिक विकारों में चिकित्सार्थ प्रयोग किया जाता है। लेकिन यदि इस औषधि का प्रयोग सही मात्रा एवं सहीरूप में न किया जाये तो इसके कई प्रतिकूल परिणाम देखने को मिलते हैं। इस अध्ययन का उद्देश पारसिक यवानी के प्रतिकूल प्रभाव को दो रूग्णों की चिकित्सा के माध्यम से प्रस्तुत करना है। पारसिक यवानी चूर्ण द्वारा बनाये हुए कैप्सूल कुछ रूग्णों में ५०० मि.ग्रा. एक बार कुछ रूग्णों में २५० मि.ग्रा. दो बार एवं कुछ रूग्णों में २५० मि.ग्रा. एक बार चित्तोद्वेग व्याधि में दी गई। ५०० मि.ग्रा. की मात्रा में पारसिक यवानी कई रूग्णों को दी गई थी लेकिन दो रूग्णों में इस मात्रा से प्रतिकूल प्रभाव दिखाई दिया। इन दोनों रूग्णों में औषध की मात्रा ५०० मि.ग्रा. से घटाकर २५० मि.ग्रा. दो बार की गई फिर भी कुछ प्रतिकूल प्रभाव मिलते रहे। अतः बाद में औषध मात्रा २५० मि.ग्रा. दिन में एक बार निर्धारित की गई। जिसके कोई भी प्रतिकूल परिणाम नही मिले। परीक्षण के परिणाम के विश्लेषण से ज्ञात हुआ कि ये दोनों ही रूग्ण पित्तप्रकृति के थे, अर्थात् पित्तप्रकृति व्यक्तियों में प्रतिकूल प्रभाव दिखाती है। जबकि यही मात्रा वात एवं कफ प्रकृति के व्यक्तियों के लिए निर्बाध है। तथा पित्तप्रकृति के व्यक्तियों के लिए २५० मि.ग्रा. दिन में एक बार की मात्रा निरापद है।