

Drug Trial

Clinical Evaluation of an Ayurvedic Remedy Trishun in Common Cold

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SUMMARY

Ayurvedic remedies are quite popular in India as also home remedies for the common cold. In an open clinical study, an Ayurvedic remedy Trishun was studied in three hundred and twelve patients having common cold with the help of twenty family physicians in their private practice. Treatment was given initially for two and a half days (5 doses) and was extended to four days (8 doses), if required.

The patients were assessed clinically for nine signs and symptoms and also on a visual analogue scale for the overall benefits.

Statistically significant improvement ($p < 0.001$) in all signs and symptoms was observed with Trishun. Adverse effects were very minimal (only in 7 out of 312 patients) and did not require withdrawal of the drug.

INTRODUCTION

Common cold or 'Flu' is one of the most frequently occurring ailment which affects every individual at one time or the other in his life span, in some cases too frequently. A wide range of medications are available for treatment. However, because of the complexity of this particular ailment and multiple factors that affect the same, the response to treatment is also variable and there are times when alternative treatment is sought for with a different approach to the disease process^{1,2}. Ayurveda, the Indian system of medicine, has been playing an important role in the health care of our population. Ayurvedic remedies are being used for day-to-day ailments, particularly with a belief of their better safety. Ayurvedic medicines

Sudarshan Ghan Vati and Tribhuvan Kirti Rasa prescribed commonly by Ayurvedic physicians are used by people also^{3,4}. A pharmaceutical product Trishun, composed of these two commonly used remedies was subjected to a clinical study in common cold & 'flu'.

MATERIAL AND METHODS

A study of this type needs a large number of patients. Twenty medical practitioners from Bombay through the offices of Insurance Medical Practitioners' Association (Ayurveda) were involved. Each medical practitioner was expected to study the effect of the drug in twenty patients.

Patients suffering from hypertension, diabetes or any other metabolic or sys-

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***List of Participant Physicians at the end.

temic disorder, and children below 12 years of age and pregnant women were excluded from the study.

The patients were assessed for the following signs and symptoms and graded between 0 as absent to 3 as severe.

1. Pulse
2. Blood pressure
3. Temperature
4. Headache
5. Bodyache
6. Fever
7. Stuffy nose
8. Sneezing
9. Sore throat
10. Cough

11. Loss of appetite and

12. Malaise.

The overall impression of the physician was graded on a visual analogue scale.

A protocol giving details of the study procedure was finalised in association with the coordinator of the physicians' group. A case record form to provide all the relevant information for each case was designed. A detailing session was conducted with the participating physicians to minimise variations in clinical graduation. The followup was done after 5 doses (2-1½ days) and after 8 doses when the treatment was extended. Wherever possible, daily evaluation was suggested.

The study took about 6 months. All case record forms were collected and after compilation were subjected to statistical analysis.

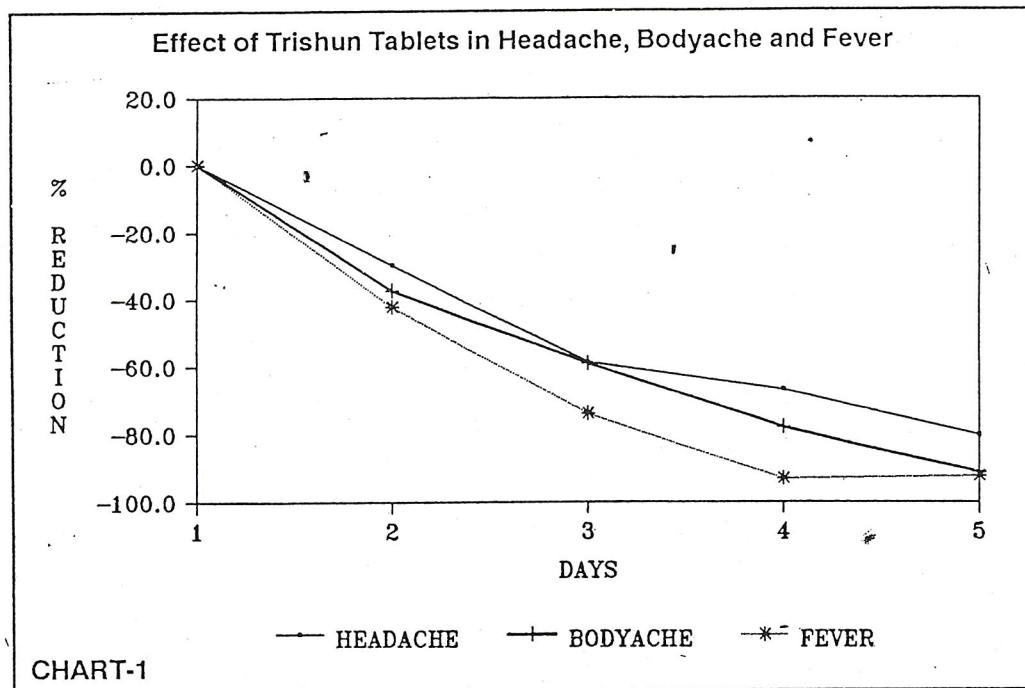
The list given in App

RESULTS

The results of the following Tal evaluation scores revealed improvement in all the symptoms with Trishun. The most significant improvement was in fever, which was obtained after 5 doses. Finally, the patients were reassessed after 1 and Chart

Of the 31 patients who required analgesic treatment before this drug.

However, by physician



Sign/Sympt
(No. of Pts.)

Headache (6)

Bodyache (7)

Fever (46)

Stuffy nose (

Sneezing (7)

Sore throat (

Cough (55)

Loss of appe

Malaise (33)

The list of participating physicians is given in Appendix-A.

RESULTS AND OBSERVATIONS

The results are presented in the following Tables and Charts. Clinical evaluation of the individual symptom scores revealed a significant improvement in all the symptoms after treatment with Trishun. After a day's treatment, all the symptoms showed a decrease to a significant extent, except loss of appetite, where the significance could be obtained after the 2nd day (5 doses). Finally, the global impression was assessed after 5 days of treatment (Table 1 and Chart 1-3).

Of the 312 patients, 8 and 10 patients required analgesic and antibiotic treatment respectively after treatment with this drug.

However, one common observation by physicians was nonappearance of

Table 2 Untoward effects of therapy	
Effects	No. of patients
Weakness	7
Dryness of mouth	2
Loose motions/diarrhoea or pain in abdomen	3
Urticarial rash	1
Burning urine/stool	1
Bitterness in the mouth	6

weakness which is normally observed after known therapy.

Other effects observed

After each daily assessment of symptoms, patients were actively questioned for adverse events, if any. The following effects were observed after initiation of the treatment. None of these was severe and no patient required withdrawal of the drug (Table 2).

Table 1 Effect of Trishun in common cold (n=312)				
Sign/Symptom (No. of Pts.)	Mean Severity Score			
	Pre Treatment	Post Treatment	Diff	P value
Headache(67)	1.344	0.269	1.075	P<0.001
Bodyache(73)	1.356	0.123	1.233	p<0.001
Fever (46)	1.392	0.109	1.283	p<0.001
Stuffy nose (55)	1.473	0.309	1.164	p<0.001
Sneezing (74)	1.379	0.203	1.176	p<0.001
Sore throat (39)	1.128	0.154	0.974	P<0.001
Cough (55)	1.164	0.309	0.855	p<0.001
Loss of appetite (32)	1.344	0.594	0.750	p<0.001
Malaise (33)	1.303	0.303	1.000	p<0.001

Effect of Trishun Tablets in Stuffy Nose, Sneezing and Sore Throat

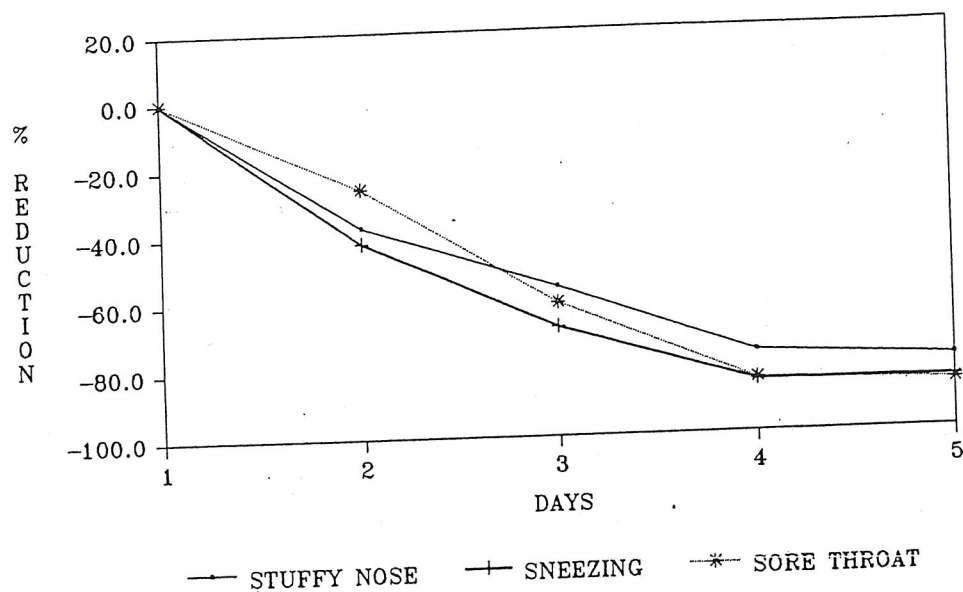


CHART-2

Effect of Trishun Tablets in Cough, Appetite and Malaise

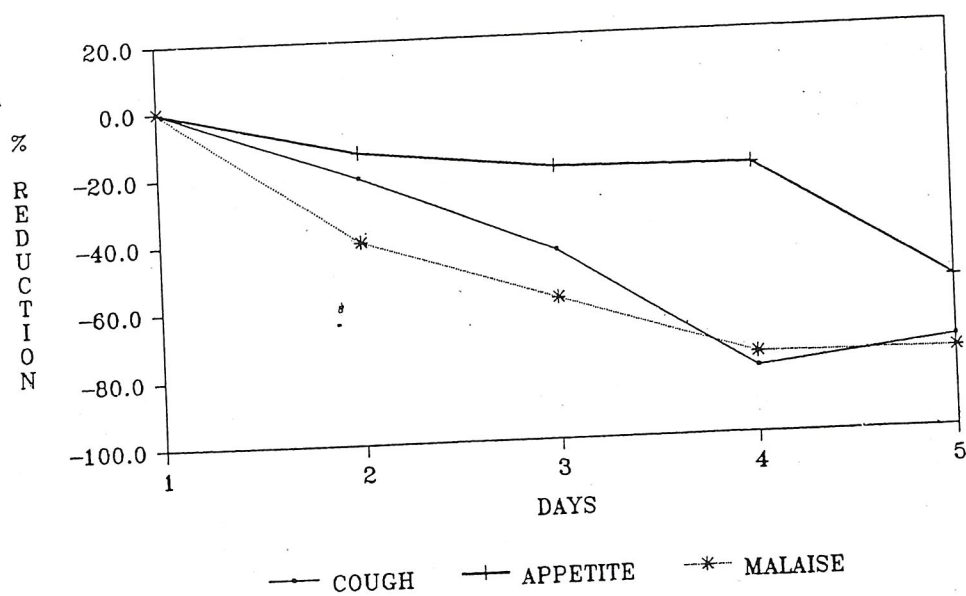


CHART-3

DISCUSSION

The common problem for their family is self-approximation of the number of consultations available in the area.

Besides antipyretics, antihistaminic agents etc. the Ayurvedic medicines and remedies for

Ayurvedic medicines be safe and effective. The study of its safety of the remedy is a drug. This safety of the remedy is also confirmed by the Ayurvedic improvement of bodyache, confirms the Kirti Rasa Jwaraghna limited effect in throat infection.

Th

DISCUSSION

The common cold is still the main problem for which people seek help from their family physicians. In fact the condition is self-limiting and clears rapidly in approximately seven days. A large number of cough and cold remedies are available in the market⁵.

Besides various analgesics and antipyretics, sedative and non-sedative antihistaminic decongestants, antimicrobial agents etc. Certain homoeopathic, Ayurvedic medicines and nasal steam inhalants are more popular as home remedies for the common cold.

Ayurvedic home remedies believed to be safe are rarely studied for their safety and efficacy. This probably is the first study of its kind on a common Ayurvedic remedy sold as an over-the-counter drug. This study not only established the safety of a compound preparation but also confirmed its specific use as per Ayurvedic principles. The better improvement observed as regards fever, bodyache, sneezing and stuffy nose confirms classical claims of Tribhuvan Kirti Rasa and Sudarshan Ghan Vati as Jwaraghna (antipyretic ?) drugs. The limited effect observed in soreness of throat indicates that this combination

may not be having typical antibacterial or anti-inflammatory effects.

In a situation when people are increasingly becoming resistant to established drugs this study validated the usefulness of Ayurvedic drugs for common ailments.

List of Participant Physicians

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There are seasons when to be still demands immensely higher strength than to act.

— Channing

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