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Clinical Study Of Polyherbal Formulation Panchkola On Life Style Disorder Pratishyaya.

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ABSTRACT: This clinical study was conducted according to a research plan known as the protocol. Panchkola has been clearly indicated in Shodashanga Hridaya for Pratishyaya chikitsa. It is proved that the main culprit of pathogenesis of Pratishyaya is Vata and kapha dosha which cause inflammation of nasal cavity, running nose, sneezing etc. Therefore, the first line of treatment is considered to restrict the production of Vata and Kapha, pachana and liquidate already produced Kapha, improve the function of Agni and use of the drug which pacifies Vata and kapha. These aims may be achieved by trial drug.

Keywords: panchkola pratishyaya nasanaha nasasrava, jwara, shirahshoola, shirogaurav, kshavathu, angamarda, nasanaha, ghranviplava, kasa, aruchi, galtaluosthashosha, swarabheda.

INTRODUCTION: Panchkola with a classical reference in Bhava Prakash Nighantu possess teekshna, ushna, Deepaka, shreshtha pachaka, kaphavatahara properties and indicated in kaphavataja vikaras like Pratishyaya. Acharya Sushruta has classified the Nidanas of Pratishyaya in Sadyojanaka and Kalantarajanaka. The Sadyojanaka Nidanas can be compared with aggravating factors. The Kalantarajanaka Nidanas are Viprakrishta Hetu whereas Sadyojanaka Nidanas are Sannikrishta Hetus. Once due to Kalantarajanaka Nidanas, Doshas are vitiated and Khavaigunya is created, the repeated contact with Sadyojanaka Nidanas cause the recurrent attack of disease. Though Pratishyaya is Tridoshaja but Vata- Kapha Doshas are dominant in this disease. Therefore panchkola is effective in pratishyaya.

AIMS AND OBJECTIVES:

The aim is to evaluate either the drugs are effective in Pratishyaya (Rhinitis) or not

The objective of the present study is to prepare safe and economical polyherbal formulation panchkola for pratishyaya.

Clinical study: The clinical work was planned to evaluate the effects of trial drugs in the management of Pratishyaya.

MATERIALS AND METHODS:

- 1. Selection of patient: The patient attending O.P.D of G.A.C.H. Patna was selected randomly on the basis of classical sign and symptoms described in various Ayurvedic texts.
- 2. Consent: Written consent was taken on prescribed proforma before the inclusion of patient in trial. They are briefed about merits and demerits of thesis protocol before taking consent.

3. Criteria of inclusion:

The patients who agree for trial.

The patients in between 15yrs -70 yrs of age.

The patients suffering from Pratishyaya.

Only uncomplicated cases were included.

4. Criteria of exclusion:

Patients who were not agree for trial.

Patients below age 15 yrs and above 70 yrs.

Patients suffering from other infectious disease.

Method of Evaluation:

Clinical screening – A detailed case history proforma was specially prepared for this purpose. All the following mentioned points were recorded in this proforma before initiating the trial. The same protocol was adopted in trial duration.

A. Pre-trial Screening:-This was done before the administration of trial.

The complete medical history was taken.

Ashtavidha and Dashavidha Pariksha (Examination) was also done and pathogenesis was explored depicting all the samprapti-ghataka.

B. Follow up screening: Once the trial was started, O.P.D. patients were called for follow up on 3rd, 7th, 15th, and 30th day to evaluate and to observe the effects or adverse effect of treatment on their clinical status.

THERAPEUTIC STUDY: Selection of trial drug:

In the present study, the drugs were selected on the basis of texual references. The constituents of Panchkola are ushna and vata-kapha nasak guna.

Collection of trial drug:

The drugs were collected from P.G. Dept. of G.A.C.H. Patna. The drugs identification, pharmacognostical and phytochemical studies have been carried out in R.R.I. (C.C.R.A.S.) unit of Lucknow.

Preparation of trial drugs:

Method of preparation – Fruit of Piper longum, Root of Piper longum, Stem of Piper retrofractum, Root of Plumbago zelevnica and Rhizome of Zingiber officinale were collected from P.G. Dept. of G.A.C.H. Patna. Firstly the macro impurities were picked from the sample. The sample was washed and dried in a shaded place. Then sample was powdered in the form of Yavkuta separately and mixed altogether. Then dosage forms were prepared and stored for dispensing in the laboratory of P.G. Dept. of G.A.C.H. Patna

METHOD OF DRUG ADMINISTRATION:

Part: Fruits of pippli, roots of pippli and chitraka, stem of chavya and rhizomes of sunthi in yavkuta form.

Formulation: Phanta.

Route: Oral.

Dose: 50 -100 ml phanta twice daily.

Sahapana: Ghrita and sugar. Duration of treatment: 30 days. Follow up: 3rd, 7th, 15th, 30th day.

Center for study: Govt. Ayurvedic College and Hospital Patna.

Pathapthya:

The patients were advised to take pathya and apathya.

Pathya - Take the hot meals.

Drink Luke worm water.

Stay in warm and heated places in winters.

Take bath with Luke warm water.

Stay indoors during pollution. (S.S.Ut 24/21)

Apathya - Do not smoke.

Avoid exposure to polluted environment.

Don"t expose directly to cold wind.

Don"t consume edible substance kept in refrigerator. (S.S.Ut.24/22)

CRITERIA OF ASSESSMENT All the patients were assessed for relief in sign and symptoms after the completion of trial. The scoring system was applied according to severity of sign and symptoms for the sound statistical analysis. The score is given individually to each sign and symptoms.

All the sign and symptoms were graded according to severity-

No exacerbation	0
Mild	1
Moderate	2
Severe	3

The observed sign and symptoms during the study were nasasrava, jwara, shirahshoola, shirogaurav, kshavathu, angamarda, nasanaha, ghranviplava, kasa, aruchi, galtaluosthashosha, swarabheda.

Overall assessment:

Total effect of therapy was assessed as follows-

% Relief in Sign & Symptoms	Overall effects
75 - 100%	Markedly improved
50 - 75%	Moderately improved
25 - 50%	Slightly improved
0 - 25%	No improvement

STATISTICAL ANALYSIS:

The scoring of criteria's assessment was analyzed statistically in term of B.T (Before treatment), A.T (After treatment), SD (Standard deviation) and SE (Standard error). The observed difference was calculated by adopting Student-'t' test.

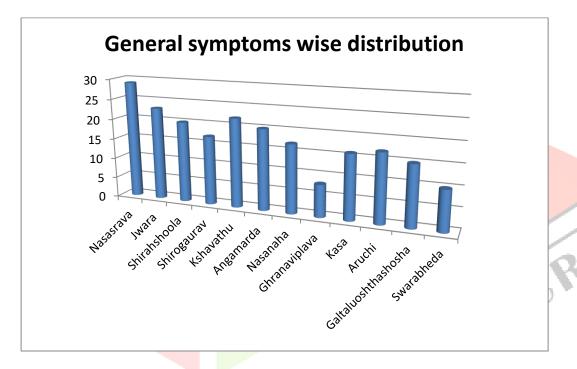
The obtained results were interpreted as follows:

P> 0.05	Insignificant.
P < 0.05	Significant.
P< 0.01	Significant.
P< 0.001	Highly significant.

In the present study, total-34 patients of Pratishyaya were registered, out of which 5 patients discontinued the treatment before completion of the course against medical advice. So they were dropped out. 29 patients completed the duration of treatment. The datas of their clinical observations are presented below –

Table no.18: General symptoms wise distribution.

S.N.	General symptom	No. of patients	%
1.	Nasasrava	29	100
2.	Jwara	23	79.31
3.	Shirahshoola	20	68.96
4.	Shirogaurav	17	58.62
5.	Kshavathu	22	75.86
6.	Angamarda	20	68.96
7.	Nasanaha	17	58.62
8.	Ghranaviplava	08	27.58
9.	Kasa	16	55.17
10.	Aruchi	17	58.62
11.	Galtaluoshthashosha	15	51.72
12.	Swarabheda	10	34.48

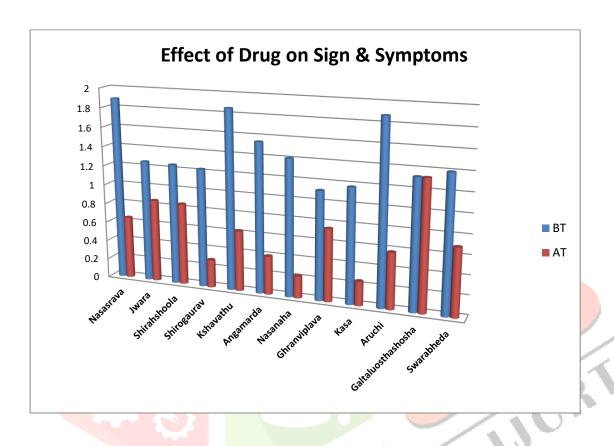


Out of 29 patients, 100% patients were suffering from nasasrava, 79.31% patients of jwara, 75.86% patients of kshavathu, 68.96% patients of shirahshoola and angamarda, 58.62% patients of shirogaurav, nasanaha, and aruchi, 55.17% patients of kasa, 51.72% patients of galtaluoshthashosha, 34.48% patients of swarabheda and 27.58% patients of ghranviplava.

Table No.19 The Effect of drug on Essential Ayurvedic Clinical Features.

S.	SYMPTOMS	MEAN		%	±SD	± SE	"t"	P
N.				Relief				
		BT	AT					
1	Nasasrava	1.89	0.65	65.45	1.12	0.20	5.95	< 0.001
2	Jwara	1.26	0.86	31.03	0.49	0.10	3.76	<0.01
3	Shirahshoola	1.25	0.85	32.00	0.50	0.11	3.55	<0.01
4	Shirogaurav	1.23	0.29	76.19	0.74	0.18	5.19	< 0.001
5	Kshavathu	1.86	0.63	65.85	0.92	0.19	6.24	< 0.001

6	Angamarda	1.55	0.40	74.19	0.74	0.16	6.90	<0.001
7	Nasanaha	1.41	0.23	83.33	0.72	0.17	6.66	< 0.001
8	Ghranaviplava	1.12	0.75	33.33	0.51	0.18	2.04	>0.05
9	Kasa	1.18	0.25	78.94	0.57	0.14	6.53	<0.001
10	Aruchi	1.88	0.58	68.75	0.91	0.22	5.80	<0.001
11	Galtaluoshthashosha	1.33	1.33	00.00	0.00	0.00	0.00	>0.05
12	Swarabheda	1.40	0.70	50.00	0.48	0.15	4.58	<0.01



The mean grade of Nasasrava before treatment was 1.89 it decreased to 0.65 with SD± 1.12 and SE± 0.20 giving a relief of 65.45% with t value of 5.95 which is highly significant at p<0.001.

The mean grade of Jwara before treatment was 1.26 it decreased to 0.86 with SD± 0.49 giving a relief of 31.03% with t value of 3.76 (p<0.01) which is significant.

The mean grade of Shirahshoola before treatment was 1.25 it decreased to 0.85 with SD± 0.50 giving a relief of 32% with t value of 3.55 (p<0.01) which is significant.

The mean grade of Shirogaurav before treatment was 1.23 it decreased to 0.29 with SD± 0.74 giving a relief of 76.19% with t value of 5.19 (p<0.001) which is highly significant.

The mean grade of Kshavathu before treatment was 1.86 it decreased to 0.63 with SD± 0.92 giving a relief of 65.85% with t value of 6.24 (p<0.001) which is highly significant.

The mean grade of Angmarda before treatment was 1.55 it decreased to 0.40 with SD± 0.74 giving a relief of 74.19% with t value of 6.90 (p<0.001) which is highly significant.

The mean grade of Nasanaha before treatment was 1.41 it decreased to 0.23 with SD± 0.72 giving a relief of 83.33% with t value of 6.66 (p<0.001) which is highly significant.

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The mean grade of Ghranaviplava before treatment was 1.12 it decreased to 0.75 with SD± 0.51 giving a relief of 33.33% with t value of 2.04 (p>0.05) which is insignificant.

The mean grade of Kasa before treatment was 1.18 it decreased to 0.25 with SD± 0.57 giving a relief of 78.94% with t value of 6.53 (p<0.001) which is highly significant.

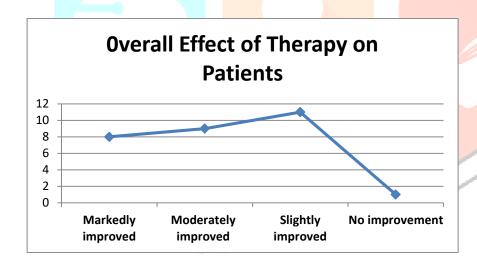
The mean grade of Aruchi before treatment was 1.88 it decreased to 0.58 with SD± 0.91 giving a relief of 68.75% with t value of 5.80 (p<0.001) which is highly significant.

The mean grade of Galtaluosthashosha before treatment was 1.33 it remains same 1.33 with SD± 0.00 giving a relief of 0% with t value of 0.00 (p>0.05) which is insignificant.

The mean grade of Swarabheda before treatment was 1.40 it decreased to 0.70 with SD± 0.48 giving a relief of 50% with t value of 4.58 (p<0.01) which is significant.

Table no.20- Overall effect of therapy on patients.

SN.	Results	No. of patients	%
1.	Markedly improved	8	27.58
2.	Moderately improved	9	31.03
3.	Slightly improved	11	37.93
4.	No improvement	1	3.44



As shown in the table no. 27, after administering Panchakola in the patients of Pratishyaya, Marked improvement was observed in 27.58% of patients, Moderate improvement in 31.03% of patients and slight improvement in 37.93% of patients. Only 3.44% of patients were those who did not show any improvement.

Discussion on Clinical Study:

After completion of therapy, results were analysed and presented statistically. The statistical data is observed as follows-

GENERAL DESCRIPTION REGARDING STUDY:

Tendency towards sedentary life style and faulty dietary habits leads to vitiation of Vatadosha and Kaphadosha.

In the present study, Apathya, the foundation stone of the treatment for Pratishyaya is concerned. Apathya should be emphasized when dealing with management aspect. Even a single time and number of Apathya used may cause reccurence of disease.

Predominance of vata, kapha & mandagni was found to play an important role. Maximum doshanubandha found as Vata and Kapha in study.

Probable mode of action:

As per classics, the therapeutic efficacy of the drugs depends upon its properties namely Rasa, Guna, Virya, Vipaka and its Prabhava. The activity of the drug may be produced by either one of these or in combination.

Panchkola with a classical reference in Bhava Prakash Nighantu possess teekshna, ushna, Deepaka, shreshtha pachaka, kaphavatahara properties and indicated in kaphavataja vikaras like Pratishyaya.

The action of drugs based on their rasa panchaka on samprapti ghatakas is as follows:

All ingradients of Panchkola have katu rasa so they increase agni that's why it causes pachan of Ama, kapha and fruitful in jwara, aruchi and angamarda.

All ingradients of Panchkola by virtue of its ushna virya act as kaphavatashamak, deepan, pachan of Ama, shothahar, vatanulomaka and shoolaprashamak. Thus they relieve symptoms of Pratishyaya eg nasanaha, nasasrava, kasa etc.

Chitraka possess lekhaniya properties so it decreases and roots out kapha. It relieves in shirogaurav, aruchi, angamarda etc.

Pippali and chitraka possess rasayana properties so they increases rogapratirodhak shakti.

Almost all the drugs have Katu rasa, katu vipaka, ushna virya and kaphvatahar property which favour sroto shodhan, there by breaking the samprapti ghataka of Pratishyaya.

Probable mode of action according to modern pharmacology:

Pippali contains piperlonguminine, piperine and pipernonaline which are antioxidant and causes anti-inflammatory activity. Pippali boost up immune status of body. Pippalimoola possess anti-inflammatory and analgesic activity. Chavya possess anti-oxidant activity. Chitraka and shunthi also possess anti-microbial, anti-allergic and anti-inflammatory activity. With all the above possible modes of action, the drug acts at every level of samprapti, therefore beneficial in Pratishyaya.

Result: First considering about sign and symptoms of Pratishyaya roga mentioned in Ayurvedic texts, the percentage relief in various symptoms was shown in the clinical study. In this study, this was observed that relief in the symptoms Nasanaha, Kasa, Shirogaurav, Angamarda, Aruchi, Kshavathu, and Nasasrava was statistically highly significant having percentage relief about 83.33%, 78.94%, 76.19%, 74.19%, 68.75%, 65.85% and 65.45% respectively. Relief in symptoms Jwara, Shirahshoola and Swarabheda was statistically significant having percentage relief about 31.03%, 32% and 50%, respectively. In symptoms, Ghranaviplava and Galtaluoshthashosha, percentage relief was 33.33% and 00.00%, respectively but these were statistically insignificant.

Probably the time period was less so the change could not be seen. A specific answer for this may be got only after further studies with longer duration of treatment.

Overall effect of therapy on patients:

After administering Panchkola in the patients, it showed Marked Improvement in 27.58% patients, Moderate Improvement in 31.03% patients and Slight Improvement in 37.93% patients. Only 3.44% patients were those who did not show any improvement.

Summary:

The clinical study is described with following aims and objectives:

-To assess the efficacy of the trial drug Panchkola on Pratishyaya.

The reference for the drug and disease was taken from "Shodashanga Hridyaya" written by Acharya Priya Vrata Sharma. Panchkola has five ingradients- Pippali, Pippalimoola, Chavya, Chitraka and Shunthi. Combining the gunas of all the ingradients, this drug has mainly ushna guna therefore kaphavatanashaka property.

All points regarding Nidana to Samprapti of Pratishyaya and its general treatment has been described in Sushruta samhita. This disease closely resembles Rhinitis. Pratishyaya was described in ayurvedic texts having kapha-vata predominance.

Clinical study of drug has been described in detail and all the data observed was presented statistically. The observed data were grouped as general consideration, effect of therapy on sign and symptoms according to ayurvedic texts and overall effect of therapy on patients. From the data of the general consideration, observation reveals that this disease affects more in middle age group persons, who faces the pollution more. From the data on effect of therapy and on ayurvedic clinical feature, observation reveals that maximum relief was observed in the symptoms nasanaha, kasa, shirogaurava, angamarda, aruchi, kshavathu and nasasrava respectively. Minimum relief was observed in symptoms swarveda, shirahshoola and jwara respectively. No any significant relief was observed in symptoms Ghranaviplava and Galtaluoshthashosha.

Pratishyaya is one of the major diseases in the present era, which mainly induced due to the inevitable pollution and life style developed gradually in society. There is no any effective treatment for Pratishyaya (Rhinitis) still today, but ayurveda may give the appropriate solution of this problem.

CONCLUSION

From the study, following conclusion can be drawn-

After administering the drug, relief in the symptoms was observed. Clinicaly Panchkola has better efficacy on symptoms – nasanaha, kasa, shirogaurava, angamarda, aruchi, kshavathu and nasasrava respectively in Pratishyaya.

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