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ROLE OF HARIDRA KHANDA IN URTICARIA

Dr. Deodatta Bhadlikar[1], Dr. Devyani Bhadlikar[2], Dr. Shruti Saxena[3*], Dr. Archana Pandey Jumle[4], Rahul Jumle[5]

[1]Conceptualization, Data Curation, Methodology and Writing Original Draft, M.D. (Ayurveda); Ph.D. (Ayurveda); DHBTC (Diploma in Herbal Beauty Therapy & Cosmetology); DCR (Diploma in Clinical Research); PDFIIM (Post Doctoral fellow of Indian Institute of Medicine): MBA (Master of Business Administration in Healthcare Management), Fellowship Course in Ayurved for Women and Maternal Health Care Management.
[2]M.D. (Ayurveda); DCR (Diploma in Clinical Research), Ph.D. (Sch.).
[3]M.D.(Ayurveda); PGDEMS (Post Graduate Diploma in Emergency Medicine), Assistant Professor, Dept. of Agadtantra Evum Vidhivaidyaka, Sardar Ajit Singh Smriti Ayurved Mahavidyalaya, Bhopal.
[4]Conceptualization, Data Curation, Methodology and Writing Original Draft, Associate Professor, Dept. of Prasutitantra & Strirog, Datta Meghe Ayurveda Medical College, Hospital & Research Centre, Nagpur.
[5]Associate Professor, Dept. of Kaumarbhritya (Paediatric), Mahatma Gandhi Ayurved College, Hospital & Research Centre, Datta Meghe Institute of Higher Education & Research (Deemed to Be University), Salod (H), Wardha, Maharashtra, India 442001.

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***Corresponding Author**
Dr. Shruti Saxena
Assistant Professor, Dept. of Agadtantra Evum Vidhivaidyaka, Sardar Ajit Singh Smriti Ayurved Mahavidyalaya, Bhopal.

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INTRODUCTION

Among the common therapeutic problems, there are probably a few ones that challenge the skill and ingenuity of the dermatologists more than that done by urticaria (Sheetapitta, Udarda and Kotha) which is mostly resistant to treatment so far known to the medical world. The present known treatment & mangement is still not an ideal one by any means.

Under the circumstances an outlook of helplessness and frustration exists still today. The present known treatment of urticaria is sometime ineffective & consequently patients suffer by this disease for months together in many cases and even relapses are very common & frequent. Due to these drawbacks they cannot be recommended as satisfactory routine treatment of urticaria. Thus, it is obvious that an ideal treatment for the cure or relief of urticaria remains to be known.

The above mentioned situation presses the need of further research on the problem of treatment and management of Sheetapitta, Udarda and Kotha. With this idea and finding the indication of a large number of single or compound drugs of herbal, mineral and animal origin in the samhitas of Indian system of medicine (Ayurveda) in the form of Choorna Decoction, Taila and Lepa, for the treatment of sheetapitta, Udarda and Kotha with claims of satisfactory results by ayurvedic physicians. This scientific therapeutic study was planned. In this therepeutic study, the validity and the potentiality of an ayurvedic medicine will be shown.

MATERIALS AND METHODS

Selection of drug

Before we select a drug for research purpose, it is essential that the drug must have some authentic background, either described in classics or based on the experience of a successful treatment. In the present context all these points have been kept in view. The drug selected for this study has classical reference and is also known as uesful for the treatment of skin diseases in general and for the treatment of urticaria (Sheetapitta, Udarda and Kotha) in particular, in Bhaishjyaratnavali.

In this book it is claimed that this drug may completely cure the condition within a week. It is also claimed that this is the best drug for treatment of itching.

Trial Drug

For the therapeutic trial in this study an Ayurvedic compound Haridrakhanda was chosen & for control the antihistaminic drug (Foristal Lon tab.) was taken. The detail of the drug is being mentioned in the following lines The trial drug Haridrakhanda was prepared as per Bhaishajya Ratnavali. The ingredients of the compound are enumerated in Table 1.

Table: Ingredients of Haridrakhanda.

S.No.	Sanskrit Name	Latin Name	Family	Parts used	Proportion
1	Haridra	Curcuma longa Linn.	Zingiberaceae	Rhizome	2400 gms.
2	Shunthi	Zingiber officinale Roscoe	Zingiberaceae	Rhizome	300 gms.
3	Marich	Piper nigrum Linn.	Piperaceae	Fruit	300 gms.
4	Pippali	Piper longum Linn	Piperaceae	Fruit	300 gms.
5	Dalchini	Cinnamomum zeylanicum Blume	Lauraceae	Bark	300 gms.
6	Laghu Ela	Elettaria cardamomum	Ziongiberaceae	Fruit	300 gms.

		Maton			
7	Tejpatra	Cinnamomum tamala Nees Ebern.	Lauraceae	Leaves	300 gms.
8	Vidanga	Embelia ribes Burm	Myrsinaceae	Fruit	300 gms.
9	Nishotha	Operculina turpethum Siiva Manso.	Convolvulaceae	Root	300 gms.
10	Amalaki	Phyllanthus emblica Linn.	Euphorbiaceae	Fruit	300 gms.
11	Haritaki	Terminalia chebula Retz.	Combretaceae	Fruit	300 gms.
12	Bivitaka	Terminalia belerica Roxb	Combretaceae	Fruit	300 gms.
13	nagkeshara	Mesua ferrea Linn.	Guttiferae	Flower	300 gms.
14	Motha	Cyperus rotundus Linn.	Cyperaceae	Root	300 gms.
15	Lauha	-	-	-	300 gms.
16	Ghrita	-	-	-	1800 gms.
17	Dugdha	-	-	-	19 kgs
18	Sharkara	-	-	-	15 kgs

Dose: 15 gms. of Haridrakhanda was used with hot water in three divided doses daily.

Subjects

The subjects included in this therapeutic trial were from the out patient department. The patients who were diagnosed as a case of Sheetapitta, Udarda and Kotha (urticaria), were subjected to this therapeutic study. Factors such as age, sex and occupation were always considered.

The patients of Sheetapitta, Udarda and Kotha had no signs of any other grave systemic disease. But a few patients had some simple and seasonal systemic diseases during the course of therapeutic trial and were not left out from the final assessment.

The diagnosis in every patient included in the study was made on the clinical grounds. In addition to history and the clinical examination. Appropriate laboratory procedures were undertaken to exclude systemic diseases.

This therapeutic study is based on total 30 cases who could continue the treatment and were followed till the end of the enquiry. The Patients who could not turn up after one week for follow-up study, are not included in the total number.

Investigations

Clinical laboratory investigations, consisting of routine haematologic evaluation, total leucocyte count, differential leucocyte count, haemoglobin percentage and erythrocyte sedimentation rate (E. S. R.) by Wintrobe Method, liver function test, blood group, urinalysis,

stool examination, fractional test meal and electrocardiogram (E. C. G.), were done before and after treatment.

Stage incidence

Out of the total 30 cases, 24 (80%) Cases were of chronic stage, while rest 6 (20%) cases were of acute stage.

Distribution of Subjects

The cases included in this study, were randomly distributed into two groups:

Group 1 (Trial Group): This group consisted of 20 (acute 3 and chronic 17) Patients. Each patient received 15 gms. of Haridrakhanda orally, in three equal divided doses, generally for 15 days. In certain cases the treatment continued for three weeks and never more than that.

Group II (Control Group): This group consisted of only 10 (acute 3 and chronic 7) patients. Each patient received Foristal Lontab. One orally, thrice daily, for 15 days, In certain cases in this gronp too, the treatment continued for three weeks and never more than that.

Diet

All the patients included in the study were instructed not to take any protein containing diet, specifically milk and its products, meat, fish, egg, all sorts of pulses and heavy diets. Otherwise all the patients was taking normal diet.

Records

The symptoms were noted, clinical photographs before and after treatment were taken and follow-up record of each case was maintained, for final assessment.

Symptoms noted

Itching and formation of wheal was recorded in all the 30(100%) cases, irritation was encounted in 25 (83.3%) cases, history of constipation was in 12 (40%) cases, low grade temperature was noted in10 (33.3%) cases, while vomiting was found in 5(16.6%) cases. Swelling of the face, lips, buccal cavity and difficulty in deglutition was found in 2 (6.6%) cases and complaint of diarrhoea was only in 1(3.3%) patient.

Clinical photographs

To assess the results of the therapy taken, both before and after treatment.

Follow-up

All the patients included in. the study, were followed up regularly, at weekly interval and were finally assessed after termination of the treatment.

Criteria of Assessment

The main criteria of assessment of the therapeutic trial was based on the complete regression of lesions. Next criteria of assessment was the satisfaction reported by the patients after total period of treatment. The results of this therapeutic study were recorded as follows in the form of improvement.

The various investigations which showed abnormality before treatment were also taken in account, while doing the final assessment. The results of this therapeutic study were recorded as follows.

Cured

The patients labelled as cured when100% regression of lesions, complete absence of the symptoms noted earlier and normalisation of haematological abnormalities, acidity, changes in T-waves and negativity in stool examination, were recorded.

Improved

The patients were labelled as improved when less than 100% regression along with some symptomatic relief & tendency towards normalisation of haematological abnormalities, acidity, changes in T-waves and negativity in stool examination, were recorded.

Stationary

The patients were labelled as stationary when no change at all, in the lesions, symptoms and in the abnormalities found in various investigetions, was recorded.

Deterioration

The patients were labelled as deteriorated when increase in the number ef lesions, exacervation of existing lesions along with severity of the symptoms and more abnormalisation in investigations were recorded.

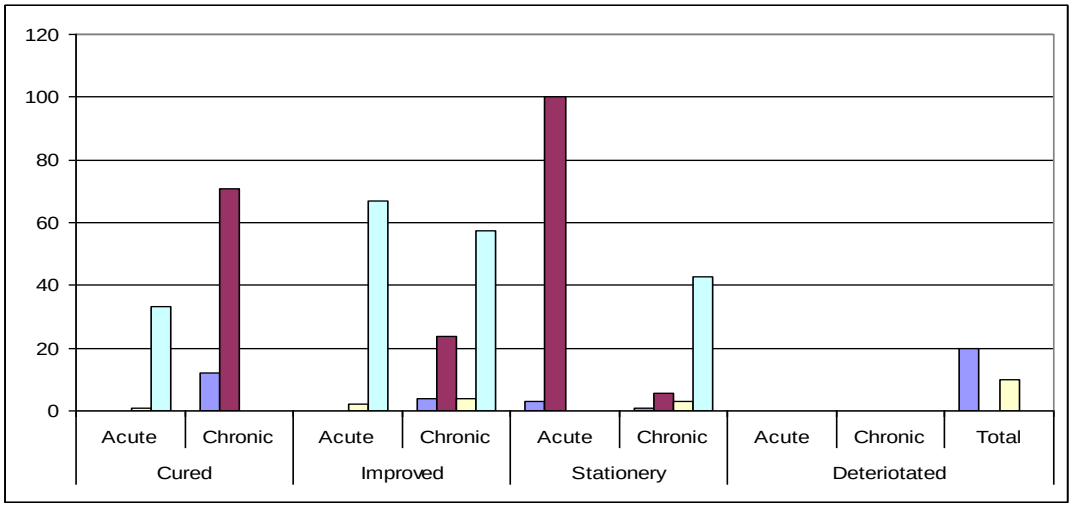
RESULT

Most of these patients were treated for 2 weeks but never more than 3 weeks before the final assessment, with either drugs, i. e. trial drug Haridrakhanda & control drug Foristal Lon-tab.

When the results of the therapeutic study were considered according to regression in lesions and relief in symptoms having, in view the percentage of improvement in minute detail, the results were noted (Table).

Table: The Detailed Results of the Therapeutic Study.

		Trial Group		Control Group	
		No.	%	No.	%
Cured	Acute	0	0.0	1	33.3
	Chronic	12	70.6	0	0.0
Improved	Acute	0	0.0	2	66.7
	Chronic	4	23.6	4	57.2
Stationery	Acute	3	100.0	0	0.0
	Chronic	1	5.8	3	42.8
Deteriotated	Acute	-	-	-	-
	Chronic	-	-	-	-
	Total	20	-	10	-



The results of this therapeutic study, having in view the abnormalities found before treatment, considering the pattern of eosinophil count, erythrocyte sedimentation rate (E. S. R.), fractional test meal and electrocardiograph (E. C. G.) are being tabulated as follows.

Eosinophil count

The result, considering the cases, who showed abnormal eosinophil count initially, but improved after treatment, has been shown in Table.

Trial group

The mean value of abnormal eosinophil count of 17 cases, who were treated with trial drug (Haridrakhanda) was 10,11, before treatment and after 15 days of treatment they were again

examined for the same, then the mean value showed marked reduction, i e. it became 5 29. The difference between the mean values before and after treatment was 4.82. The t & P values before and after treatment are given in the table. The statistical analysis showed that there was significant reduction in eosinophil count of course within normal limit, after the treatment, by Haridrakhanda.

Table: Results of the Treatment on Eosinophil Count.

Groups	Values	Before Treatment	After Treatment
Trial Group	Mean	10.11	5.29
	±S.D.	8.26	3.16
	Comparison between before and after treatment	t = 2.23	
		P < 0.05	
Control Group	Mean	11.36	5.72
	±S.D.	6.13	4.16
	Comparison between before and after treatment	t = 2.20	
		P < 0.05	

Control Group

The mean value of abnormal eosinophil count of 8 patients who received the control drug (Foristal Lon-tab) was 11.36 before teatment and after 15 days of the treatment when they were examined for the same, the mean value showed marked reduction i.e, it became 5.72. The difference between the mean values before and after treatment was 625. Thet and P values are given in the table. The statistical analysis showed that there was significant reduction in eosinophil count, of course within normal limits, after the treatment by Foristal Lon-tab, too.

When the difference between the two mean values before and after treatment in both the groups i, e, trial and control, were compared, apparently it was observed that the reduction in eosinophil count was more in control group (Foristal Lon-tab-treated group), but when the difference mean values (t-0.70; IP 0.05) were statistically analysed, it was found that they were insignificant, which means that the reduction in eosinophil count of course within normal limits, was almest equal in both the groups.

Erythrocyte sedimentation rate

The result considering the cases. who showed abnormal erythrocyte sedimentation rate (E.S.R.) initially, but improved after treatment, has been shown in table 4.

Table-4: Results of the Treatments of Erythrocyte Sedimentation Rate.

Groups	Values	Before Treatment	After Treatment
Trial Group	Mean	23.46	11.69
	±S.D.	11.64	5.78
	Comparison between before and after treatment	t = 3.23	
		P < 0.005	
Control Group	Mean	15.00	13.2
	±S.D.	3.87	4.14
	Comparison between before and after treatment	t = 0.71	
		P < 0.25	

Trial group

The mean values of erythrocyle sedimentation rate in 13 cases of the group was 23.46 mm. for Ist hour, by Wintrobe method, before treatment. After 2 weeks of the treatment, E. S, R. was again estimated and then the mean value showed marked reduction i.e. becames 11.69mm for Ist hour. The difference between the mean values before and after the treatment, was 11.77 mm for Ist hour, The statistical data suggest that Haridrakhanda Causes significant reduction in E.S.R.

Control Group

The mean value of erythrocyte sedimentation rate, in 5 cases of this group, was 15.00 mm. for Ist hour, by Wintrobe method, before the treatment, After 2 weeks of the treatment. E.S.R. was again estimated & then the mean values showed reduction, i.e. it became 13.2 mm for Ist hour. The difference between the mean values before and after treatment, was 1.8 mm. for Ist hour, The Statistical analysis shows that Foristal Lon-tab has insignificant reduction in erythrocyte sedimentation rate (E.S.R.).

When the difference between the two mean values before and after treatment in both the groups i, e. trial and control, were compared and statistically analysed, it was noted that the reduction in erythrocyte sedimentation rate (E. S. R.) was more and significant in trial group in comparison to control group.

Free hydrochloric acid

The result, considering the cases, who showed abnormal degree of free hydrochloric acid (hypochlorhidria) initially, but improved after the treatment, has been shown in table 5.

Trial group

The mean of free hydrochloric acid and S.D. were calculated before and after the treatment. Before the treatment, the mean values of hydrochloric acid were very much decreased (low), but after the treatment the mean values of free hydrochloric acid increased (high). Its t and P values were also calculated in every sample (fasting, Ist, 2nd, 3rd, 4th & 5th) after the treatment, showed statistically highly significant increase in free hydrochloric acid, i.

Table-6: Results of the Treatments on Free Hydrocloric Acid.

Groups	Fasting	First	Second	Third	Fourth	Fifth
Trial Group						
Before Treatment						
Mean	6.06	3.08	9.13	10.0	6.86	3.86
±S.D.	4.41	3.77	3.87	4.83	3.44	3.04
After Tretment						
Mean	22.13	17.93	26.46	26.33	23.00	20.00
±S.D.	13.30	8.88	5.68	5.85	13.34	8.14
Statistical t	4.41	5.69	9.81	8.34	4.45	5.07
Comparison b/w before and after treatment P	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Control Group						
Before Tretment						
Mean	7.8	5.0	9.0	11.2	7.2	4.0
±S.D.	3.34	3.60	2.64	4.56	4.60	4.0
Statistical t	0.6	0.9	0.12	0.78	1.29	0.60
Comparison b/w before and after treatment P	0.001	0.20	0.001	0.001	0.10	0.001

Control group

The mean of free hydrochloric acid and S.D. were calculated before and after treatment and it was noted that the level of free hydrochloric acid in every sample was neither increased nor decreased in any case of the group. The t and P values were also calculated in every sample and were found statistically significant.

When the difference between the two mean values before and after treatment in both the group i.e. trial and control, were compared and statistically analysed, it was noted that the increase in free hydrochloric acid was more and significant in trial group, in comparison to control group.

Electrocardiograph

The result, considering the cases, who showed changes in their electrocardiograph initially, but improved after treatment has been shown in table.

Table 6: Results of the treatment on Electrocardiograph (ECG).

Groups	No. of Cases	Before treatment changes in E.C.G.	After Treatment	
			Improved	Stationary
Trial group (Haridrakhanda)	5	Inverted T-L3, avF	+	-
		Flat T-Li, L2, V5-6	+	-
		Flat T-avF, V2	+	-
		Inverted T-AVL	+	-
		Inverted T-Li, Flat AVL	-	+
Control Group (Foristal Lontab)	2	Inversion T-L3 over damped V2-5	+	-
		Flat T-LI, AVR, V6	-	+

The cases who were labelled as cured and/or improved showed normalcy in their T-waves changes. While the cases who remained stationary after treatment in both the groups i.e. trial and control, could not show any normalcy in their T waves changes.

When the results of the treatments were compared considering the changes in electrocardiograph, it was observed that the cases of both the groups showed normalcy equally in both the groups, with the subsidence of the lesions. But the cases, who remained stationary even after treatment, the groups, could not show any normalcy in their T-waves changes. Thus it is obvious that the results obtained on this parameter, was altogether similar in both the groups, i. e. trial and control.

OBSERVATIONS

In general the improvement seemed to be more dependent on the total time & frequency of use of the trial and control drugs, than on the age of the patients, duration of the disease or extent of involvement of the body surface.

Response to any treatment varies in different individuals with regard to completeness of the results, in cases of urticaria. It may begin within a few days, but it is after one week the maximum satisfactory effect is evident. Generally, urticaria of acute nature or of shorter duration responds better than that of the chronic nature and of the longer duration. Its response can not be detected in patients within a week of treatment, then the chances of

improvement are very remote. Consequently, the treatment should be dis- continued because the patients are unlikely to respond to further therapy.

Mostly the cases of urticaria who developed the disease due to some stress, could not show any improvement or very negligible improvement, which could not ba taken into account for final assessment.

When recovery begins, the observant physician will be able to note the improvement The dorsum of the hands and feet showed less and less affected but if they get affected the improvement will be less and very slow. In comparison to that the lesions over fleshy areas such as the face, abdomen or axilae, get rapid and complete subsidence.

Regression of the lesions at the optimum level may, in cases, require maintenance dosage even after 15 days of treatment by either drug i. e. Haridrakhanda and Foristal Lon-tab.

Observation in the patients who failed to respond to the treatment, showed the following active reasons.

1. Poor nutritional status and digestion.
2. Idiopathic: No definite reason could be established.

Regression appeared to be of permanent nature if the treatment could be continued for sufficiently long time. The topical treatment would stand no chance to cure the disease, because the cause of the disease is undoubtedly and mostly systemic, Hence, the experience says that the topical treatment has no place in the treatment of urticaria.

Most of the patients on either drug i. e. on Ayurvedic compound drug ‘Haridrakhanda and Foristal Lon tab, showed some beginning of regression within three days after the onset of treatment. Those that could not show regression within a week of the treatment, almost failed to show any regression afterwards & remain stationary regarding response of the treatment, such patients were six in number, including both the groups i.e. trial and control.

Another commonly noted finding with oral therapy is the fact that it should be continued for a sufficiently long time because having the drug off or reducing the dose would produce a relapse of the disease process. Younger patients respond faster and more completely than that done by older ones.

Toxic Reactions

Toxic reactions of mild to moderate degree in the form of drowsiness were noted with Foristal Lon-tab therapy after a few days treatment. No toxic reaction either of mild or moderate nature was noticed in any of the cases receiving 'Haridrakhanda' of course a few of younger patients could not relish the taste of the compound.

DISCUSSION

In the absence of aspecific drug various medicaments have been tried from time to time all over the world, with no satisfactory results. It is still the most difficult problem due to non availability of a specific drug, for all cases, for the treatment of the disease. Hence, it was felt necessary and urgent to conduct research for better therapy.

Since a large number of single drugs or their compounds are in use in indian system of medicine, for the treatment of the disease, with claims of satisfactory results, but without any controlled clinical trial. Under the circumstances, with a view to assess the validity of one compound drug, namely 'Haridrakhanda' this study was planned.

The results of the study, when were considered according to regression in the lesions and relief in symptoms, it was noted that the chronic patients receiving Ayurvedic compound drug 'Haridrakhanda', were found to be better than those who were receiving the control drug 'Foristal Lon-tab'. While, the acute cases, who were receiving 'Haridrakhanda', could not show any improvement in their clinical or pathological condition. Where as the cases of control group, who were receiving Foristal Lon-tab, showed definite improvement in their clinical condition. But Foristal Lon-tab, was not very effective in chronic cases, in comparison to 'Haridrakhanda'.

The above results obtained on the various drugs reveal that Haridrakhanda is relatively more effective in the treatment of urticaria, in comparison to Foristal Lon tab. But it is clear from the study, that both have effective property for the treatment of urticaria.

Statistical comparison between the results obtained on patients receiving Haridrakhanda and cases getting Foristal Lon-tab, showed a highly significant change in improvement, considering lesion regression, which indicates the effectiveness of 'Haridrakhanda' in treatment of urticaria. But this result does not mean that Foristal Lon tab, is not at all

effective, it only means that 'Haridrakhanda' is more effective than the control drug Foristal Lon tab.

The comparison of the results obtained on Ayurvedic drug 'Haridrakhanda' with the results obtained on Foristal Lon-tab. gave highly significant deviation and indicates that the Ayurvedic drug is far more superior than the modern drug, having in view, the abnormalities found before and after treatment, considering the pattern of eosinophil count, erythrocyte sedimentation rate (E.S.R.) fractional test meal and electrocardiograph, (E.C.G.) too.

The trial drug has never produced any toxic or untoward effect, which may lead to discontinuation of the therapy, even after the period of one month continuous use of course a few of younger patients could not relish the taste of the compound.

Therapy depends on finding the cause and then instituting suitable treatment. Many acute wide spread attacks are associated with diarrhoea and perhaps with vomiting, in these there is often a definite history of the symptoms developing a few hours after taking some special, and usually exotic food, e. g. crab, oysters or other shellfish. Or there may be a straight forward history of a drug such as procaine penicillin being given and the reaction developing soon after, In these and in analogous cases suitable advice can easily be given. It is in the chronic urticarias that great difficulty in discovering the cause may be encountered. Urticarias which present as attacks on which small, itching, round discs appear are often examples of stress reactions and one probably due to acetylcholine release; they do not respond to antihistaminic drugs.

In a difficult case, all aspects of the patient and his life must be considered. What he eats and drinks, what drugs he takes, what he inhales, the foci sepsis he Possesses, his emotional stressess-these & all other possible factors must be assessed. Patch tests are of no use in most cases.

If the eruption is caused by insect bites, liberal dusting of the patient, his clothing, bedding, his animals and their quarters with disophane powder will rapidly effect a cure.

The causes of urticaria are manifold. It is a great and all too common error to believe that every urticarial manifestation must necessarily, be of allergic origin. Moreover, it should be stressed most emphatically that it is by no means enough to identify and eliminate the

exciting factors, for it is often equally important to discover and wherever possible eradicate the predisposing factors in order to achieve a lasting cure.

In more than one third of all our cases digestive disorders were found to play an etiologic role. Urticaria is a disease of complex rather than single causation, with regard to both the predisposing & the exciting causes. For this reason it seems necessary to consider the etiology and pathogenesis of urticaria not only from the viewpoints, e. g. food allergy, gastrointestinal disturbances, & metabolism, but also from a more comprehensive point of view so that the reader will be able to appreciate the complexity of the problem and be guided as to the therapeutic measures to be applied.

CONCLUSIONS

1. The Ayurvedic compound ‘Haridrakhanda’ is effective for the treatment of urticaria.
2. The total results of the therapeutic study reveal that Ayurvedic drug compound ‘Haridrakhanda’ is a better potent drug.
3. Sex has no role to play in therapeutic response.
4. The experience gained during the cause of therapeutic trial, suggests that the drug tried, is safe to use for petty long time with no toxic effect.
5. The hypotheses observation and results of the study open the door for further research on the problem, than antihistaminics.
6. The Ayurvedic drug compond 'Haridrakhandha' may have a place in the management of urticaria.