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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF TRIKATU AND SITA CHOORNA AND HARIDRA KHANDA IN THE MANAGEMENT OF SHEETAPITTA (ITCH SEVERITY SCALE)

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ABSTRACT

Sheetapitta is one of the important and most common allergic skin diseases described in Ayurveda. Vata and Kapha which are primarily disturbed in this disease. This in turn is associated with Pitta resulting in Tridosha vitiation leading to redness, wheals and itching on the skin. Mandala (round patch), Utsedha (Wheals), Kandu (itching), Toda (Pricking pain) are the main signs and symptoms along with Chardi (vomiting), Jwara (fever) and Daha (burning sensation) are the associated symptoms of Sheetapitta. It can be correlated to various types of Urticaria in modern parlance. Sheetapitta, Udarda and Kotha are described by Brihatrayee as symptoms of many diseases. It is a Pitta Pradhana Tridosha conditions described first time in a special chapter by Acharya Madhava. Trikatuchurna which contains Shunti, Pippali and Maricha are having Katu Rasa, Madhura Vipaka, Ushna Virya. **Objective-** To assess the efficacy of Trikatu and Sita Churna in the management of Sheetapitta. **Material and Methods-** Non randomized comparative clinical study. Study group received Trikatu Churna with Sita (Group A-56 subjects) and Control group receives Haridra Khanda (Group B-50 subjects) from OPD and IPD of SDM college of Ayurveda and

hospital, Hassan, Karnataka. **Result-** The effect of intervention was assessed through using itch severity scale (ISS) before and after treatment. Trikatu Churna (group A) and Haridra Khanda (group B) showed statistical significance after one month of intervention. **Conclusion-**Administered of Trikatu Churna with Sita (group A) and Haridra Khanda (group B) is effective in the management of Sheetapitta (itch severity scale) for a period of one month.

Keywords: Itch severity scale (ISS), Sheetpitta, Tridosha, Trikatu Churna, Udarda, Urticaria

INTRODUCTION-

In Ayurveda, allergic manifestation is mentioned under the concept of Satmya-Asatmya (compatible-non compatible). It manifests due to exposure to Asatmya Ahara Vihara and contact with different allergens **[1]**. Sheetapitta (urticaria) is one of the common clinical conditions and its incidence is 15-25% among all type the of dermatological condition. Kandu, Varatidamshtavat Shotha, Ragavarnata are cardinal signs and symptoms of Sheetapitta. Urticaria affects around 20% of people at some point in their lifetime. The discomfort and distress caused by Urticaria can lead to serious impairment of quality of life **[2, 3]**. Urticaria involves only the superficial portion of the dermis, presenting as well-circumscribed wheals with erythematous raised serpiginous borders with blanched centers that may coalesce to become giant wheals **[4]**. Urticaria is a type of urticaria that is caused by a brief increase in capillary permeability. Swelling last less than 24 hours **[5]**. Trikatu, as per Bhaisajyaratnawali is a compound herbal formulation containing three Tikta Dravyas mixed together in equal quantities. Dried fruits of Piper nigrum (Maricha) and Piper longum (Pippali) and dried rhizomes of *Zingiber officinale* (Shunthi) are used to prepare this miraculous formulation.

Chemistry of Trikatu- Trikatu contains the three herbs *P. longum, P. nigrum, and Z. officinale*. Piperine is the major chemical as well as a biological marker in the component herbs *Piper longum* and *Piper nigrum*, with other ingredients in lesser amounts. Gingerols, Gingiberene, Shagols, and other chemical compounds can all be found in *Z. officinale*.

Chemical composition of *P. longum* - Long pepper contains piperine, which is the main and active ingredient. The piperine content is 3–5% (on dry weight basis) in *P. longum*. The fruit of *P. longum* contains a large number of alkaloids and related compounds, the most abundant of which is piperine, methyl piperine, iperonaline, piperettine, pellitorine, piperlongumine, piperlonguminine, asarinine, piperundecalidine, refractomide A, pipercide, piperderidine, longamide and tetrahydropiperine,

terahydropiperlongumine, dehydropiperno-naline piperidine, pregumidiene, brachy-stamide, brachystamide-A, brachystine, terahydropiperlongumine, and trimethoxy cinnamoylpiperidine. Sesamin, pulvuatilol, fargesin, and other lignans have also been isolated from P. longum fruit. Volatile oil of the fruit *P. longum* is a complex mixture. Major components of essential oil are caryophyllene and pentadecane (both about 17.8%) and bisaboline (11%) along with volatile piperine. Other components include thujine, terpinoline, p-cymene, p-methoxy acetophenone, and dihydrocarveol **[6]**.

Chemical Composition of *P. nigrum*- *P. nigrum* contains lignans, alkaloids, flavonoids, amides, and other aromatic compounds along with approximate 3.5% of volatile oil. Sabinene, pinene, linalool, limonene, and phellandrene are all components of essential oils. *P. nigrum's* chemical identifier is piperine, an alkaloid. Piperine is also available in the form of chavicine, which is an isomer of piperine. The aroma of black pepper is not attributed to piperine or chavicine. Piperine is responsible for pungency of the black pepper **[7]**.

Chemical Composition of *Z. officinalis* - Ginger has around 450 components, according to a thorough chemical analysis. The major composition of ginger rhizomes is carbohydrates (50–70%), lipids (3–8%), terpenes, phenolic compounds, amino acids, raw fiber, ash, protein, phytosterols, vitamins, and minerals. Volatile terpenoidal constituents of *Z. officinale* include zingiberene, β-bisabolene, α-farnesene, α-curcumene, and β-sesquiphellandrene. Phenolic compounds include gingerol, paradols, and shogaol. The pungency of Ginger is due to gingerols and shagols. These gingerols and shogaols can be detected in concentrations of up to 20%–25%. Other gingerol- or shogaol-related chemicals found in ginger rhizome include 6-paradol, 1-dehydrogingerdione, 6-gingerdione, and 10-gingerdione (1–10 percent). 4-gingerol, 6-gingerol, 8-gingerol, and 10-gingerol, as well as diarylheptanoids. The characteristic odor and flavor of ginger are due to a mixture of volatile oils such as shogaols and gingerols **[8]**.

Objective- To assess the efficacy of Trikatu and Sita Churna in the management of Sheetapitta.

Material and Methods-Non randomized comparative clinical study. Study group received Trikatu Churna with Sita (Group A-56 subjects) and Control group receives Haridra Khanda (Group B-50 subjects) from OPD and IPD of SDM college of Ayurveda and hospital, Hassan, Karnataka.

Ethical Committee Approval Number- PU/PIA/IECHR/2019/80

Clinical Trial Registry of India - CTRI/2020/08/027062

Diagnostic criteria- Clinical features of Sheetapitta as mentioned in texts of Ayurveda and features of urticaria in modern text.

Inclusion criteria

1. Patients showing and also with history of classical clinical features of Sheetapitta.
2. Patients of either sex in the age group of 18-60 years.

Exclusion criteria

1. Patients suffering from any other systemic disorders like HTN, DM, IHD and HIV.
2. History of Anaphylaxis to medicine.
3. History of Angioedema.

Intervention

Group A (Trikatu Churna with Sita)- Administration of three grams Trikatu Churna mix with Sita (sugar) 20 gram with Anupana of Ushna Jala (warm water) twice daily for 30 days.

Group B (Haridra Khanda)- Administration of three grams Haridra Khanda with Anupana of Ushna Jala (warm water) twice daily for 30 days.

Urticaria activity score-

Wheal numbers score-

0=< 10 small wheals

1=10-50 small wheals or < 10 large wheals

2= > small wheals or < 10-50 large wheals

3= Almost whole body is covered

(Small wheal=< 3 cm in diameter, large wheal= > 3 cm in diameter)

Grade of itch-

0= None

1= Mild

2= Moderate

3= Severe

Urticaria activity score= Wheal numbers score+ Itch grade

ISS-Before intervention

ISS 1-1st visit

ISS 2 – 2nd visit

ISS 3- 3rd visit or after intervention.

Observation-

Distribution on the basis of group- Among the 113 registered subjects, 56 subjects completed the study in group A with 2 drop outs and 50 subjects completed the study in group B with 5 drop outs.

Distribution on the basis of age-Among the 113 subjects of Sheetapitta showed that, 29 (25.7%) subjects were in the age group of 26-30 years which shows maximum,27 subjects (23.9%) were in the age group of 46-50 years and 25 subjects (22.1%) were in the age group of 36-40 years, 12 (10.6%) subjects were in the age group of 21-25 years, 9 (8.0%) subjects were in the age group of 31-35 years, 5 (4.4%) subjects were in the age group of 51-55 years, 3 (2.7%) subjects were in the age group of 41-45 years, 2 (2.8%) were in the age group of 16-20 years and 1 (0.9%) subject was in the age group of 56-60 years.

Distribution on the basis of gender- Among 113 patients registered for this

study majority of them were females i.e. 70 patients (61.9%) and rest were males i.e. 43 patients (38.1%).

Distribution on the basis of Ahara Vidhi - Out of 113 patients registered for this study 58(51.3%) patients were following Vishamashana, 37 (32.7%) were following Adhyashana, 10 (8.8%) were following Virudhashana and 8(7.1%) patients were following Samashana.

Distribution on the basis of Purvarupa- Among 113 patients registered for this study, majority of patients i.e. 106 patients were having Rakthalochana, 98were having Anga Gaurava as Purva Rupa, 70 patients were having Dehasada, 47 patients were having Pipasa, 27 patients were having Hrullasa, 25 patients were having Aruchi.

Distribution on the basis of Rupa

Out of 113 patients registered for the study, in 113 patients each Varatidamstavat Shotha, Kandu, Jwara, Kshanikotpatti Vinasha, was present, 99 patients Toda was present, 42 patients were having Vidaha and 9 patients Chardi was present.

RESULTS

Table 1: Total ISS score in Group A (Trikatu Churna+ Sita)- Friedman test

Parameter	$X^2(2)$	P Value	Remark
ISS Score	137.125	<0.0001	S

There was statistical significance on total ISS Score in Group A, $x^2 = 137.125$, $p<0.0001$. As the Friedman test was significant post hoc test was done

Table 2: Total ISS score in Group A (Trikatu Churna+ Sita)- Wilcoxon Signed Rank Test

Parameter	Negative Ranks			Positive Ranks			Ties	Total	Z value	P Value	Results
ISS Score	N	MR	SR	N	MR	SR					
ISS-ISS1	33	18.86	622.50	4	20.13	80.50	19	56	-4.089	<0.0001	S
ISS1-ISS2	52	29.33	1525.00	3	5.00	15.00	1	56	-6.326	<0.0001	S
ISS2-ISS3	47	30.13	1416.00	7	9.86	69.00	2	56	-5.799	<0.0001	S
ISS-ISS3	55	28.85	1587.00	1	9.00	9.00	0	56	-6.436	<0.0001	S

The intervention was significant in ISS and ISS1, ISS1 and ISS2, ISS2 and ISS3, ISS and ISS3.

Table 3: Total ISS score in Group B(Haridra Khanda)-Friedman test

Parameter	$X^2(2)$	P Value	Remark
ISS Score	127.138	.000	S

There was statistical significance on total ISS Score in Group B, $x^2 = 127.138$, $p<0.0001$. As the Friedman test was significant post hoc test was done.

Table 4: Total ISS score in Group B (Haridra Khanda) -Wilcoxon Signed Rank Test

Parameter	Negative Ranks			Positive Ranks			Ties	Total	Z value	P Value	Results
ISS Score	N	MR	SR	N	MR	SR					
ISS-ISS1	24	14.96	359.00	5	15.20	76.00	21	50	-3.061	0.002	S
ISS1-ISS2	47	24.94	1172.00	1	4.00	4.00	2	50	-5.990	<0.0001	S
ISS2-ISS3	45	27.73	1248.00	5	5.40	27.00	0	50	-5.894	<0.0001	S
ISS-ISS3	50	25.50	1275.00	0	.00	.00	0	50	-6.154	<0.0001	S

The intervention was significant in ISS and ISS1, ISS1 and ISS2, ISS2 and ISS3, ISS and ISS3

Table 5: Comparative effect of Trikatu Churna with Sita and Haridra Khanda on Sheetapitta (itch severity score)– Mann Whitney U Test.

Parameter	Mean Rank		Sum of rank		U value	P Value	Results
	Group A	Group B	Group A	Group B			
ISS Score	48.70	58.88	2727.00	2944.00	1131.000	0.089	NS
ISS1 Score	47.54	60.17	2662.50	3008.50	1066.500	0.035	S
ISS2 Score	47.04	60.73	2634.50	3036.50	1038.500	0.022	S
ISS3 Score	53.38	53.63	2989.50	2681.50	1393.500	0.967	NS

The intervention was significant in ISS1 and ISS2 comparative effect of Trikatu Churna with Sita and Haridra Khanda on Sheetapitta (itch severity score).

DISCUSSION

Administration of Trikatu Churna with Sita for one month compared to Group B after intervention followed by the administration of Haridra Khanda. Haridra Khanda is having more Kaphahara Dravyaslike Haridra, Trikatu, Triphala, Nagakeshara etc. which are more effective to reduce KahaPitta Dosha and Kandu (itching).It was statistically significant in the improvement in frequency of itch in morning to night in both the group as both Trikatu Churna with Sita and Haridra Khanda are having Kaphahara property and morning is the time for Kapha Vruddhi. Consumption of the above medicines will aid to minimize chance of Kapha Prakopa and itching in other time of the day like noon, evening and night **[9-11]**.

CONCLUSION

Sheetapitta being a common and tortuous disease needs effective treatment. Assessment of vitiated Doshas and treatment targets to main vitiated Dosha is main principle of treatment of all the diseases and also in Sheetapitta along with avoidance of etiological factors. Trikatu Churna with Sita and Haridra Khanda are having Kaphahara property reduce the severe itching in urticaria. Administered of Trikatu Churna with Sita (group A) and Haridra Khanda (group B) is effective in the management of Sheetapitta (itch severity scale) for a period of one month.

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