

**Clinical Evaluation of Navakarshika Guggulu on Sheetapitta (Chronic Urticaria)**

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ABSTRACT

Sheetapitta (Urticaria) is a type I hypersensitivity reaction which is manifested because of exposure to such allergens. Epidemiology of Urticaria is increasing now days due to Industrialization and Agriculture. Sign and Symptoms of Urticaria resembles with Kotha, Udarda, Sheetapitta. Kotha is one of the Symptom mentioned by our Acharyas when body exposed to asatmyaj Ahara and Vihara. Eg. Contact with poisonous material and sheeta vayu etc. Study is conducted to evaluate efficacy of Navakarshika Guggulu on Urticaria basing on this concept. The present paper intends to highlight the utility of drug in reducing sign-symptoms and recurrence of the disease.

INTRODUCTION

The word "allergy" is derived from the ancient Greek word allos meaning "other" and ergon meaning "work". Allergy is one of four forms of hypersensitivity and is formally called as type I (or Immediate) hypersensitivity. Allergic reactions are distinctive because of excessive activation of certain white blood cells called mast cells and basophils by a type of antibody called ImmunoglobulinE (IgE). This reaction results in an inflammatory response which can range from mild discomfort to grave consequences.

Skin allergies frequently cause rashes, or swelling and inflammation within the skin, which is known as a "wheal and flare" reaction characteristic of hives [Urticaria] and angioedema. "Urticaria is a recurrent, transient, cutaneous swelling with erythema which resolves within 24 hours without leaving any residual cutaneous signs."

In Ayurveda, allergic manifestation is mentioned under the concept of satmya-asatmya.¹ It manifests due to exposure to asatmya ahara-vihara and contact with different poisonous materials (allergens). Symptoms of allergic skin reaction is mentioned as kotha in Brihata Trayi later on it is developed as separate disease under the title Sheetapitta-Udarda-Kotha by Madhavakara.²

Disease Review

Madhava nidana explained detail nidana panchaka of 'Sheetapitta-Udarda-Kotha'. He only mentioned 'sheeta maruta sparsha'³ as causative factor but in charaka samhita we can find many causative factors, which are summarized below

*Nidana***Table 1:** Nidana mentioned in Charak Samhita

1.	Rakta Dusti	Raktapradoshaja Vikara, Raktarshe dushita rakta nigraha, Raktaja Vikara etc.
2.	As Symptom in other Diseses	Poorvarupa of Kushta, Punaravartaka Jwara, Sannipatic Jwara, Nanatmaja Pittavikara, Nanatmaja Kaphavikara, Poorvarupa of Unmada etc
3.	Faulty Ahara and Vihara	Santarpana Janya Vikara, Chhardi Nigrahaja vikara, Diwaswapnajanya Vikara , Contact with various poisonous materials i.e. bathing water, oil massage, clothes, ornaments etc., Symptom of Amashayagata visha, Intake of Dooshivisha etc

*Rupa***Table 2:** Rupa [symptoms] of Sheetapitta-Udarda-Kotha.

S. No.	Rupa	S. No.	Rupa
1.	Varati dashta samsthana Shotha	5.	Jwara
2.	Kandu bahula	6.	Vidaha
3.	Toda bahula	7.	Sotsanga saraga mandala
4.	Chardi	8.	Ksanikotpatti vinasha

Samprapti

Samprapti is defined as the process involved in the pathogenesis of a disease by vitiated doshas which are constantly circulating in the body. The first and foremost person to describe the samprapti of Sheeta-pitta-Udarda-Kotha is Madhavakara in Madhav Nidana, as other Acharyas have just repeated the same thing.

Prakupita Vata and Kapha (Pradushtau Kapha Marutau) due to 'Sheeta Marutadi Nidana (Sheeta Maruta Samsparshat) – when being mixed with 'Pitta' (Pittena Saha Sambhooya) spreads internally and externally (bahir-antah visarpatah) and results in to 'Sheeta-pitta-Udarda-Kotha'.⁴

Samprapthi Ghataka

Dosha	: Tridosha
Agni	: Manda
Doshagati	: Vriddhi, Tiryak, Shakha
Vyadhimarga	: Bahya
Dushya	: Rasa, Rakta
Srotas	: Rasavaha, Raktavaha
Srotodushti prakara	: Vimarga Gamana
Udbhava Sthana	: Aamashaya
Vyakti Sthana	: Tvak
Svabhava	: Ashukari
Dosha	: Tridosha
Agni	: Manda
Doshagati	: Vriddhi, Tiryak, Shakha
Vyadhimarga	: Bahya
Dushya	: Rasa, Rakta
Srotas	: Rasavaha, Raktavaha
Srotodushti prakara	: Vimarga Gamana
Udbhava Sthana	: Aamashaya
Vyakti Sthana	: Tvak
Svabhava	: Ashukari

The aim of the present study was to evaluate effect of an Ayurvedic formulation Navakarshika Guggulu in patients of chronic Urticaria .

MATERIALS AND METHODS**Selection of Patients**

Total no. of 35 diagnosed cases of Chronic Urticaria were selected from OPD. and IPD. of S.V.Ayurvedic hospital, Tirupati, irrespective to their age, sex, occupation, religion etc basing on inclusion criteria and registered in the present clinical study; out of them 05 cases dropped out. Detailed evaluation and follow up studies were performed on specifically designed proforma on the basis of modern and Ayurvedic parameters.

Administration of Drug

Navakarshika Guggulu is prepared according to classics in S.V.Ayurvedic Pharmacy, Tirupati in capsule form of 1gm. Eranda Tailam 20-30 ml was given at bed time for Kostha shuddhi before the date of starting the medication. Then cap. Navakarshika Guggulu 1gm was given in 2tid doses after food with hot water for 45 days.

Type of Trial – Single blind open trial**Rasapanchaka of Navakarshika Guggulu****Table 3:** Properties of Ingradients⁵

Dravya	Rasa	Guna	Veerya	Vipaka	Karma
Haritaki	Pancharasa, Kashaya++, Alavana,	Ruksha, Laghu,	Ushna	Madhura	Tridoshaghna, Rasayana, Kusthanashaka.
Vibhitaki	Kashaya	Ruksha, Laghu,	Ushna	Madhura	Kapha-Pittanut.
Amalaki	Pancharas (Lavanvarjit)	Ruksha	Sheeta	Madhura	Tridosha Shamaka, Rasayana.
Pippali	Katu	Snigdha, Laghu.	Anushna	Madhura	Vatakaphahara, Rasayana.
Guggulu	Tikta, Kashaya, Katu	Sara, Tikshna, Laghu, Ruksha, Sukshma, Vishada, Pichhila,	Ushna	Katu	Kapha Vatahamaka, Pittakara, Rasayana, Kothanashak, Kusthahara.

Selection of Cases**Inclusion Criteria**

1. Age and sex- 10 to 60 years of either sex.
2. Chronicity – above six weeks.
3. Kandu – Pruritus
4. Daha – Burning sensation
5. Toda – Pricking pain
6. Varatidashta Sansthanam Shotha – Swelling
7. Frequent attacks

Exclusion Criteria

1. Acute Urticaria
2. Diabetes Mellitus
3. Hypertension
4. Tuberculosis
5. Pregnancy

Criteria for Assessment

Assessment was done under the two headings, subjective and objective assessment.

Subjective Assessment

Main signs and symptoms and associated complaints were given different scores according to their severity, they were recorded before and after treatment and during the follow up study [if there is any history of relapse]. The severity of main signs and symptoms have been recorded during the relapse. Results of the treatment were assessed on the basis of comparison of scores recorded before treatment, after treatment and after relapse (if any).

Table 4: Grading of subjective symptoms

Symptoms	Score	Grade	Grading criteria of symptoms
Kandu Daha Toda	0	None	Not present
	1	Mild	Present but not annoying or troublesome
	2	Moderate	Troublesome but not interfering with normal daily activities or sleep
	3	Intense	Severe pruritus, burning, pricking pain which is sufficiently troublesome and interfering with normal daily activities or sleep
Varatidamsta Sansthanam Shotha	0	None	Not present
	1	Mild	Up to 25% skin involvement
	2	Moderate	25- 50% skin involvement
	3	Severe	51–75% skin involvement
	4	Intense	More than 75% skin involvement
Frequency of Attacks	0	None	No
	1	Mild	Once in 4-5 days
	2	Moderate	Daily once
	3	Severe	Daily twice
	4	Intense	At any time and more than two

Objective Assessment

Under the objective parameters laboratory findings were assessed as follows: ESR and DC is done in before and for each follow up. Data is statistically analyzed by using t test.

Criteria for Assessing the Total Effect

Considering the overall improvement experienced by the patients in signs and symptoms, the total effect of the therapy has been assessed as follows:

Table 5: Criteria for assessing the total effect of Drug

Cured	100% relief in signs and symptoms
Not cured	No significant relief in signs and symptoms
Relapsed	Appearance of signs and symptoms after complete cure
Moderate relief	Above 50% relief in signs and symptoms
Mild relief	Below 50% relief in signs and symptoms

Statistical Analysis

The obtained information was analyzed statistically in terms of mean score (x), Standard Deviation (S.D.), Standard Error (S.E.). Paired t-Test was carried out at the level of 0.05, 0.01, and 0.001 of P levels.

P > 0.05- Insignificant;

P < 0.05- Significant P < 0.01 and < 0.001- Highly Significant]

Presentation of Data

The data collected and analyzed has been depicted in the following sequence:

1. General observations viz. age, sex, religion etc.
2. Results of therapy evaluated on the basis of improvement in symptomatology as well as biochemical parameters.

OBSERVATIONS

The general observations of 30 patients of Chronic Urticaria registered in this study are as follows:

Age: Maximum number of patients observed i.e. 46.66 % belonged to age group of 36-45 years. This indicates more incidence of Sheeta Pitta [Chronic Urticaria] in 4th and 5th decade; probable reasons may be predominance of Pitta in this age. Rasa and rakta are the seats of Pitta and these are the dhatus were sthanasamsraya occurs; therefore this age group may be more susceptible to Sheeta Pitta.

Sex : Male and Female patients has shown the ratio 53.33 % and 46.67% respectively, actually Chronic Urticaria is more common in Females than in Males but here little higher occurrence is observed in Males.

Habitat : Maximum prevalence (50%) of Chronic Urticaria is observed in Suburban area this may be due to allergy from exposure to agriculture pollutants.

Occupation : It is found more common in House Wives (36.67 %) may be because of indoor allergy to household poisons, water etc.

Agni : Maximum occurrence i.e. 70% of diseases was found in Agnimandya state it explains the importance of Agnimandya in disease manifestation. It leads to production of Amavisha, Tridosha prakopa which interns initiates the pathogenesis of Urticaria.

Diet : Maximum number of patients i.e. 90% were Non-vegetarian. This may be due to protein allergy.

Predominant Rasa : Maximum percentage of patients i.e.86.66% were taking diet predominant in Amla rasa. Excessive intake of Amla rasa vitiates Kapha-Pitta dosha and intern vitiates rakta which is important dushya of disease.

Prakriti : Observations regarding Prakriti of the patients showed that maximum number of patients i.e. 46.66 % belonged to Vata-Pittaja followed by Vata-Kaphaja [40%] type of Sharira Prakriti. This shows the predominant incidence of Sheeta Pitta [Urticaria] in Vata-Pittaj Sharira Prakritis as these doshas plays vital role in samprapti of Sheeta Pitta.

Koshtha: Observations of this series showed that maximum number of patients i.e. 53.33% were having Krura Koshtha. Accumulation of malas and their stagnation in the koshtha for longer duration obstructs the anuloma gati of vata resulting tiryak gati of Vata dosha.

Etiological Factors: Observations of etiological factors showed that maximum number of patients i.e. 90% shown Dadhi sevana followed by 86.66% having Amlarasa sevana, Sheetaamaruta sparsha in 63.33% of patients. This shows the importance of Vata and Pitta in disease manifestation. Excessive intake of dadhi without following rules results in vitiation of Kapha, Pitta and rakta which are mainly involved in the pathogenesis of Urticaria. Sheeta sparsha provokes the pathogenesis.

Chief Complaints: Observations of 30 patients showed that all patients i.e 100% were having Kandu and Varatidasta sansthanam shotha while Daha and Toda were found in 90% and 63.33 % of patients respectively. Above observations indicates that Itching and Rash are the cardinal symptoms of Urticaria.

Onset: Majority of the patients i.e. 90% were having history of Sudden Onset while 10% having Gradual.

Frequency of Attacks: The series showed that maximum patients i.e. 80% patients were having daily once attack while twice a day attack found in 6.66% and more than two

were found in 10% of patients. This indicated the commonest Frequency of Attack observed in Chronic Urticaria was once a day.

Chronicity: It was observed that maximum number of patients i.e. 50% were having Chronicity up to one year.

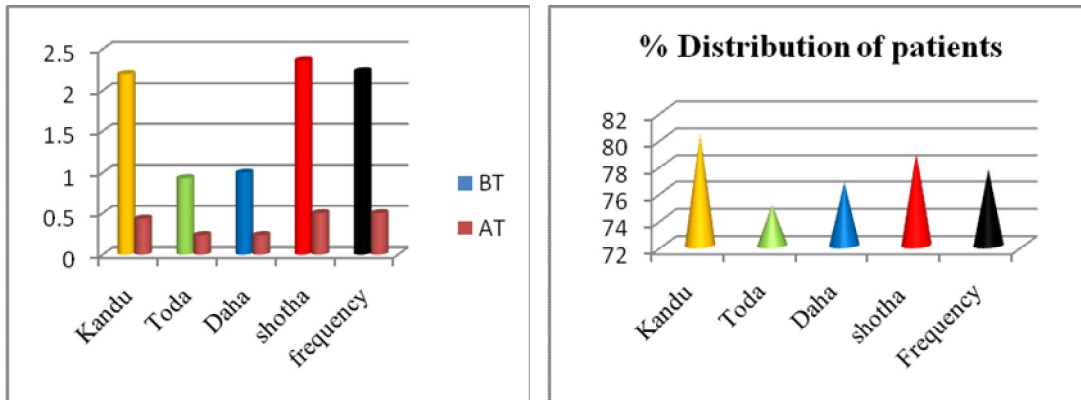
Type of Urticaria: Maximum number of patients i.e. 90% were having common chronic type of Urticaria. It shows that higher incidence of Common Chronic Urticaria compared to other forms of Urticaria.

EFFECT OF NAVAKARSHIKA GUGGULU

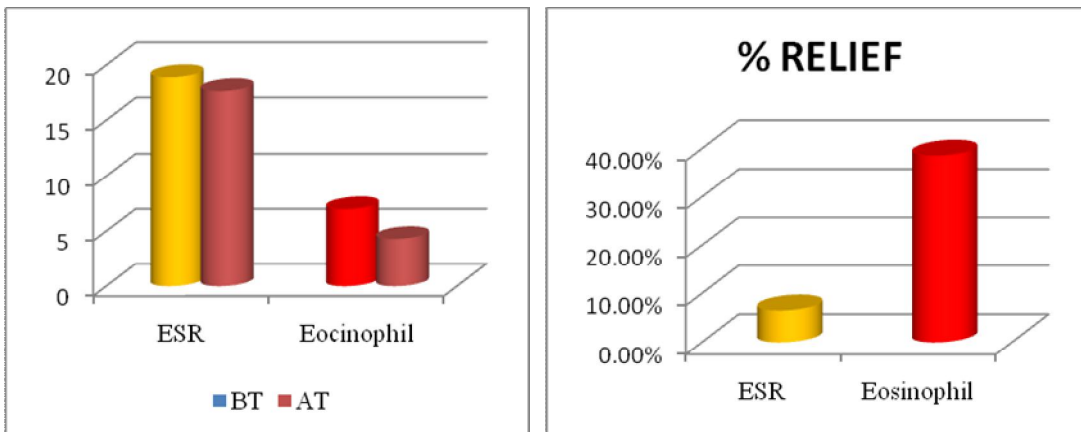
Kandu : Statistically highly significant relief (p< 0.0001) of 80.30% was observed.

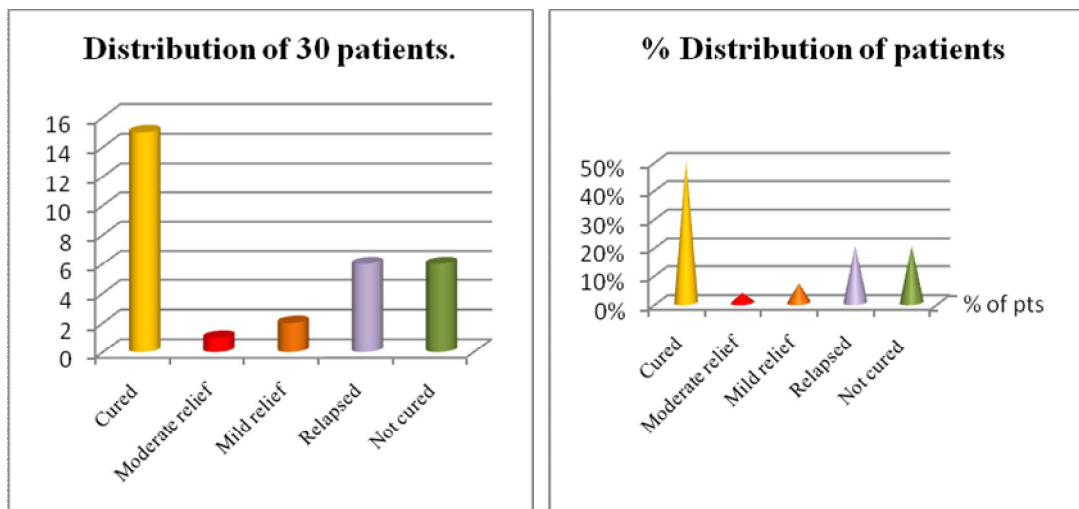
- Daha : Statistically highly significant relief (p< 0.0001) of 76.67% was observed.
- Toda : Statistically highly significant relief (p< 0.0001) of 75% was observed.
- V.S.Shotha : Statistically highly significant relief (p< 0.0001) of 78.87% was observed.
- Frequency : Statistically highly significant relief (p< 0.0001) of 77.61% was observed.
- ESR : Statistically highly significant relief (p< 0.0033) of 6.51% was observed.
- Eosinophil : Statistically highly significant relief (p< 0.0001) of 38.52% was observed.

Graph-1: Symptomatic Evaluation of the Effect of Navakarshika Guggulu.



Graph-2: Evaluation of efficacy of drug basing on biochemical parameters



Graph-3: Overall Assessment of Clinical trial.**Follow up Study**

The observations showed that 50% of patients have reported no relapse within follow up study while 20% of the patients reported relapse within 2 months of follow up study.

DISCUSSION

Kotha is the purvarupa of Kustha and Kustha is vairodhika aharajanya vikara.⁶ Urticaria in modern science can be correlated with "Sheetapitta-Udarda-Kotha" in Ayurveda. Treatment principle of vairodhika aharajanya rogas is applied.

तद्यथा--वमनं विरेचनं च तद्विरोधिनां च द्रवाणां संशमनार्थमुपयोगः
तथा-विधेश्च द्रव्यैः पूर्वमभिसंस्कारः शरीरस्येति १०४

Here Charaka explained the importance of vamana and virechana in the management of allergic disorder.

अभिसंस्कार इति सततोपयोगेन शरीरभावनम्। तथाविधैरिति रसायनप्रयोगैः।

Word 'tathavidai' indicates the role of Rasayana dravyas in the treatment of allergic manifestation.⁷ Drug Navakarshika Guggulu is selected from Sheetapitta-Udarda-Kotha adhikara of Bhavaprakasha owing to its Rasayana, Agnideepana and Virechana property.

Mode of action of the selected Drug: The present drug, Navakarshika Guggulu constitutes Triphala, Pippali and Guggulu as main ingredients. The probable mode of action of these drugs can be attributed to Tridosha samana, Rasayana, Deepana and Pachana properties. These drugs may be acting by stimulating agni and digesting the aama, clearing the srotases and ultimately producing prashasta rasa-raktadi dhatus. Triphala and Pippali acts as virechana dravyas and Guggulu has malashodhana property which helps in proper expulsion of doshas.

Pippali and Haritaki are having Anti histaminic property^{8,9} and Pippali is a Mast cell stabilizer¹⁰. Immunomodulator action of Amalaki and Pippali was proved. Guggulu is having

potent anti-inflammatory action which helps in relieving Urticaria.

The aim of the present study was to evaluate effect of an Ayurvedic formulation Navakarshika Guggulu in patients of chronic Urticaria. Symptomatic relief was observed in 80.30%, 76.67%, 75%, 78.87% and 77.61% cases regarding Kandu, Daha, Toda, V.S.Shotha and in Frequency of Attack. Mean ESR level drooped from 18.9 to 17.7, similarly mean Eosinophil count drooped from 7 to 4.3 in the 45 days of study.

CONCLUSION

After study it was understood that Sheetapitta can be considered as Asatmyaja / Vairodhika aharaja vikara and Charaka's treatment principle of Vairodhika aharaja vikara can be followed successfully.

Navakarshika Guggulu was highly significant in relieving Vartidasta samsthana shotha, Kandu and also in reducing the Frequency of attack, Daha and Toda with p value < 0.0001. It reduced E.S.R. to certain extent and normalized Eosinophil count.

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