

A PILOT STUDY OF SIDDHA DRUG *NILAVAGAI CHOORNAM* (INTERNAL) AND *SANJEEVI THYLAM* (EXTERNAL) FOR THE TREATMENT OF *KANAKADI* (URTICARIA)

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ABSTRACT

Objective: The study was designed to evaluate the therapeutic effectiveness of *Nilavagai chooranam* (internally) and *Sanjeevi thylam* (externally) for the treatment of *kanakadi* (Urticaria). **Methods:** The study was conducted at the National institute of Siddha, Tambaram sanatorium, Chennai, India. 20 patients were recruited with an inclusion and exclusion criteria. The patients were treated with 1gram of *Nilavagai chooranam* along with ghee twice a day and *Sanjeevi thylam* (externally) for a period of 48 days. The clinical effectiveness of the drug was assessed by blood parameters and UAS7 scale prior to and after the treatment. **Result and discussion:** Most of the patients

showed good improvement during the trial period with respect to the symptoms. None of the patients showed any adverse effect. The results were analyzed statistically which revealed a significant ($p < 0.05$) improvement in the treatment of *kanakadi*. **Conclusion:** Thus, it is concluded that the trial drug *Nilavagai chooranam* (internally) and *Sanjeevi thylam* (externally) is very effective and safe for the management of *kanakadi*.

KEYWORDS: *Siddha, Kanakadi, Nilavagai chooranam, Sanjeevi thylam, UAS7 scale.*

INTRODUCTION

Siddha system of medicine has a distinctive approach to care specific ailments and also to build up the immunity power of the person being treated against all diseases. In *Siddha* system of medicine, the diseases are classified into 4448 types. In the text *Sirappu*

maruthuvam, the symptoms of *Kanakadi* are itching, wheal formation, erythematous localized swelling of skin which is correlated to Urticaria in Modern medicine. Urticaria is a non-contagious skin disease which is characterized by the sudden appearance of itching, wheals of varying size and shape from very small circumference lesion. The wheals disappear within 24 hours without any treatment. Urticaria is commonly called hives, characterized by pale or erythematous localized swelling of the skin that vary in size and shape without surface swelling. The itching may be so intense that it interferes with sleep. Urticaria is a vascular reaction of the skin characterized by the appearance of wheals, surrounded by red halo or flare associated with sever itching, stinging or pricking sensation. These wheals are caused by localized edema.

Epidemiology

The lifetime prevalence rate of 8.8% has been reported. The worldwide incidence is 0.1%-3% of the population with women getting affected twice more likely than men. It is estimated that about 1 in 5 people will have urticaria once in their lifetime and this seems to be the case across all the age groups.

Race: No variation in the race.

Sex: More common in women (60%)



Figure 1: Urticarial lesions in hand.



Figure 2: Urticarial lesions in thigh.

MATERIALS AND METHODS

STUDY TYPE	:	Open clinical trial (pilot study)
STUDY PLACE	:	National Institute of Siddha, Ayothidasar pandithar hospital Tambaram sanatorium, Chennai 47.
STUDY PERIOD	:	48 days
SAMPLE SIZE	:	20 patients.
APPROVED BY	:	Institutional Ethical Committee.
IEC NO	:	NIS/IEC/10/2016-17/20-20.05.2016

Ingredients of Trial Drugs**1. Nilavagai chooranam (Internal medicine)****Table no. 1: Ingredients of Internal medicine.**

No	Name of ingredients	Part used	Quantity
1.	Nilavagai (<i>Cassia senna</i>)	Whole plant	350 gms
2.	Milagu (<i>Piper nigrum</i>)	Seed	8.75 gms
3.	Kadukkai (<i>Terminalia chebula</i>)	Fruit	8.75 gms
4.	Thandrikkai (<i>Terminalia bellirica</i>)	Fruit	8.75 gms
5.	Seeragam (<i>Cuminum cyminum</i>)	Seed	8.75 gms
6.	Vaalulvai (<i>Celastrus paniculatus</i>)	Seed	8.75 gms
7.	Sirunagaa poo (<i>Mesua ferrae</i>)	Flower bud	8.75 gms
8.	Elam (<i>Elettaria cardamomum</i>)	Seeds	8.75 gms
9.	Ilavangapattai (<i>Cinnamomum verum</i>)	Bark	8.75 gms
10.	Kadughurogini (<i>Picrohiza kurroa</i>)	Root	8.75 gms
11.	Sivadhai (<i>Operculina turpethum</i>)	Root	8.75 gms
12.	Thalisapathiri (<i>Taxus baccata</i>)	Leaves	8.75 gms
13.	Jathikkai (<i>Myristica fragrans</i>)	Fruit	8.75 gms
14.	Kirambu (<i>Syzygium aromaticum</i>)	Flower	8.75 gms
15.	Thippili (<i>Piper longum</i>)	Fruit	8.75 gms
16.	Seviyam (<i>Root of Piper nigrum</i>)	Root	8.75 gms
17.	Indhuppu (<i>Sodium chloride impura</i>)	-	8.75 gms
18.	Koogaineer (<i>Maranta arundinacea</i>)	Tuber	8.75 gms
19.	Chukku (<i>Zingiber officinale</i>)	Dried rhizome	8.75 gms

Method of Preparation

The raw drugs were dried, powdered separately and then mixed well together and equal amount of white sugar was added and preserved in a tightly closed container.

Dosage: 1gram b.d (*Verukadi*)

Adjuvant: Ghee

2. Sanjeevi thylam (External medicine)

Table 2: Ingredients of External medicine.

No	Ingredient name	Part used	Quantity
1.	Kothamalli vithai (<i>Coriadrum sataivam</i>)	Seed	280 gms
2.	Seeragam (<i>Cuminum cyminum</i>)	Seed	35 gms
3	Karpogi (<i>Psoralea corylifolia</i>)	Seed	70 gms
4	Senpaga poo (<i>Magnolia champaca</i>)	Flower	35 gms
5	Kichili kizhangu (<i>Curcuma zedoaria</i>)	Tuber	17.5 gms
6	Nalennai (<i>Gingely oil</i>)	-	1.3 lit

Method of Preparation

The above mentioned raw drugs were powdered and made into decoction. The prepared decoction was mixed with oil and boiled till it reached semi solid consistency (*mezhugu patham*).

Dosage: Quantity sufficiency (for external application and oil bath).

Inclusion Criteria

- Age: 18 –50 years
- Sex: Both male and female
- Presenting with Itching, wheal formation, swelling.
- Patient wishing and allowing treatment to be carried out, written consent must be attend.
- Willing to attend OPD for 48days

Exclusion Criteria

- Suffering from any other autoimmune diseases.
- Narcotic addicts
- Pregnancy and Lactation
- Diabetic mellitus
- Hypertension
- Any other systemic illness

Assessment Criteria

Changes in the clinical feature of the patients were noted in the Performa every week up to 7 weeks consequently with six months follow up period. The effect of treatment was evaluated on the basis of the changes in the signs and symptoms, AEC count in the blood and Ig E. Effect of therapy was assessed on the basis of UAS 7 (Urticaria assessment scale).

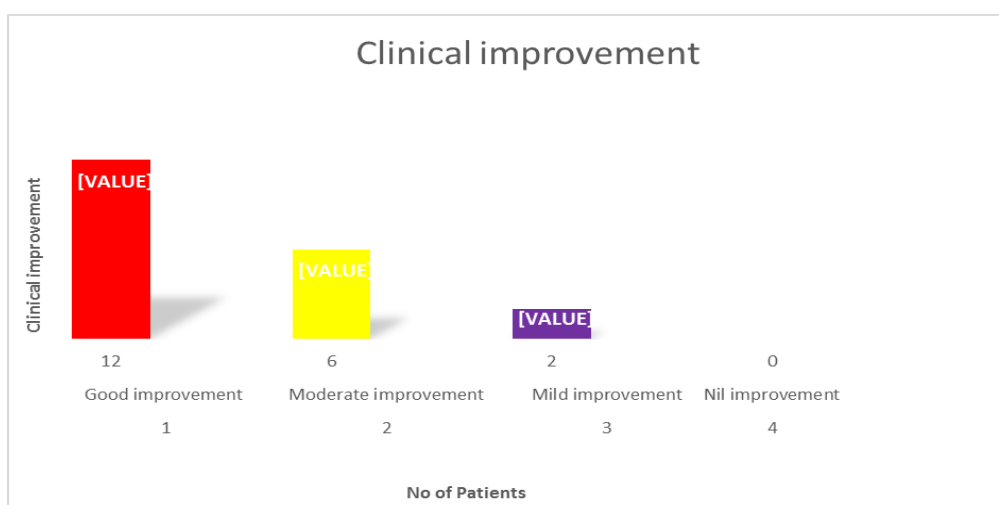
Table 3: Assessment of disease activity in patients with CIU (UAS 7scale).

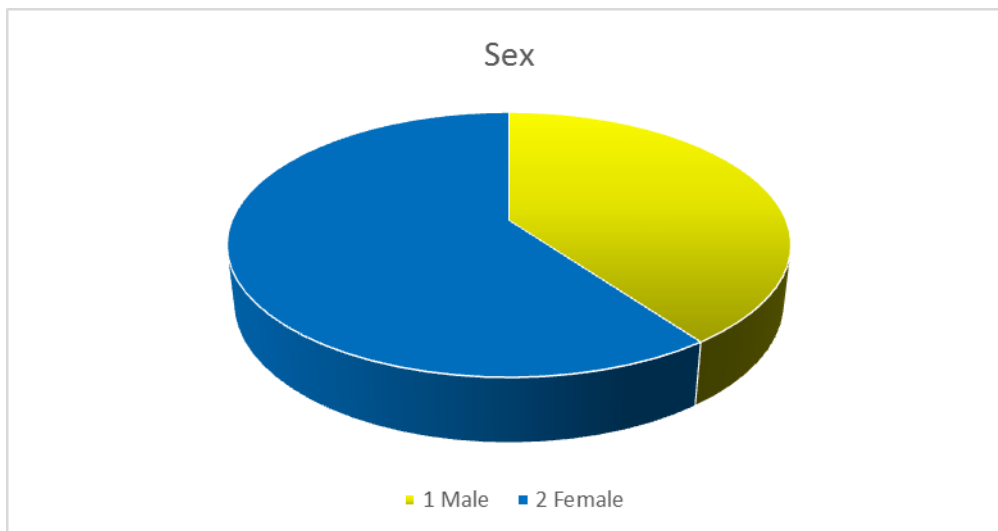
Score	Wheals	Pruritus
0	None	None
1	Mild (less than 20 wheals/24 hours)	Mild (present but not annoying or troublesome)
2	Moderate (20-50 wheals/24 hours)	Moderate (troublesome but does not interfere with normal daily activity or sleep)
3	Intense (more than 50 wheals/24 hours or large confluent areas of wheals)	Intense (severe pruritus, which is sufficiently troublesome to interfere with normal daily activity or sleep)

RESULTS

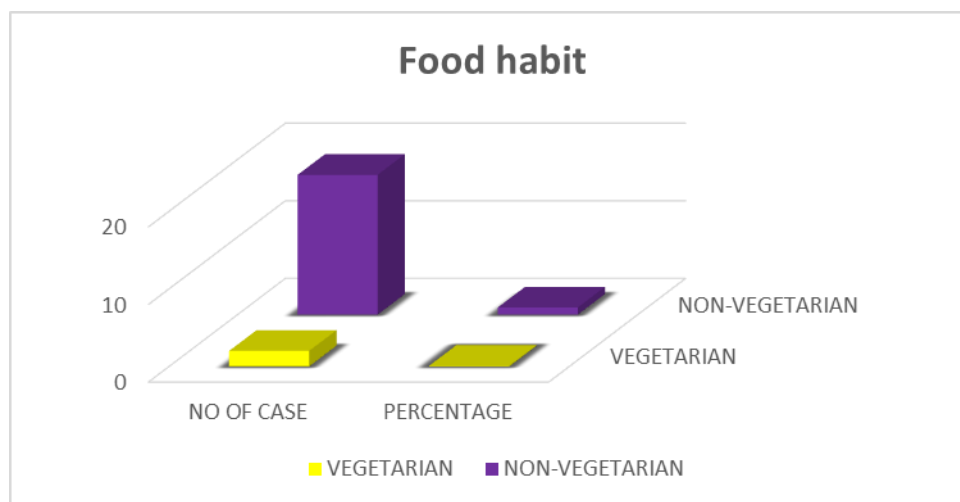
Table 4: Treatment outcome.

Case no	Age / sex	Before treatment	After treatment	Improvement
1.	22/male	Moderate	None	Good
2.	27/male	Mild	None	Good
3.	19/female	Moderate	Mild	Moderate
4.	29/female	Intense	Mild	Moderate
5.	32/female	Moderate	None	Good
6.	42/male	Mild	None	Good
7.	38/male	Moderate	None	Good
8.	37/female	Moderate	None	Good
9.	23/female	Mild	None	Good
10.	39/female	Moderate	Mild	Moderate
11.	21/male	Intense	Moderate	Mild
12.	49/female	Moderate	Mild	Moderate
13.	24/female	Mild	None	Good
14.	29/male	Moderate	Mild	Moderate
15.	36/male	Mild	None	Good
16.	36/female	Moderate	Mild	Moderate
17.	20/female	Moderate	None	Good
18.	29/female	Mild	None	Good
19.	28/male	Intense	Moderate	Mild
20.	31/female	Mild	None	Good

**Bar diagram: 1 Clinical improvement of patients.**



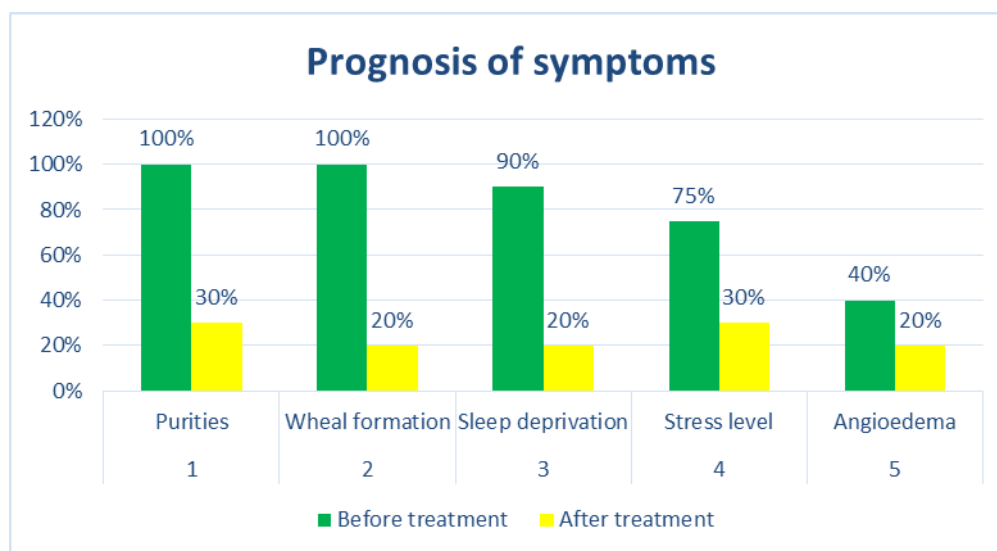
Bar diagram: 2 Sex distribution.



Bar diagram: 3 Prevalence of food habit.

Table 4: Prognosis of symptoms.

No	Symptoms	Before treatment	After treatment
1.	Purities	100%	30%
2.	Wheal formation	100%	20%
3.	Sleep deprivation	90%	20%
4.	Stress level	75%	30%
5.	Angioedema	40%	20%



Bar diagram: 4 Prognosis of symptoms.

DISCUSSION AND CONCLUSION

Urticarial reactions involve mast cell degranulation with the release of histamine and other vasoactive mediators. This leads to local capillary dilatation, internal permeability, localized edema, erythema and nerve fiber activates causing mild to intense purities.

The ingredients of *Nilavagai chooranam* has anti-histamine activity, anti-inflammatory activity and immunomodulatory activity. *Sanjeevi thylam* as an external application soothes the skin and reduces the itching. The adjuvant ghee also has the activity of anti-inflammatory. 20 patients were selected randomly based on the inclusion and exclusion criteria, out of this 12 patients showed a very good improvement with no recurrence of symptoms. 6 patients showed moderate improvement and 2 patients showed mild improvement with mild itching. Patients were asked to come for follow up sessions for 3 months after completing the treatment course. Out of 20 patients, 12 patients were female and remaining patients were male. The disease prevalence is high in non-vegetarian people compared to vegetarian. (In allopathic system, the patient was treated with 2nd generation non-sedating antihistamines like loratadine, desloratadine, fexofenadine, cetirizine and first generation sedating anti histamines such as promethazine. While having these medicines patients felt drowsiness, loss of appetite, apathy in daily activities and the symptoms may re-occur).

After treatment, blood parameters did not show much improvement. Patients seem to feel good prognosis within few days. There is no recurrence history, even though they continued their usual food habits and patient who suffered with allergic rhinitis and dry cough were

symptomatically improved. In moderate improvement cases, patients had itching sensation when exposed to allergic conditions. In mild improvement cases, they had itching and wheal formation occasionally. Angioedema lesions occurred occasionally.

Based on the result of this study, it is proved that *Nilavagai chooranam* (internal) and *Sanjeevi thylam* (external) is effective for the treatment of Urticaria (*kanakadi*).

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