

“Clinical study to evaluate the efficacy of *Kanchanar Gutika* in the management of *Galaganda* w.r.t. Hypothyroidism”

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Abstract

Hypothyroidism is defined as the failure of the Thyroid Gland to produce sufficient Thyroid hormone to meet the metabolic demands of the body. Untreated Hypothyroidism can contribute to Hypertension, Dyslipidemia, Infertility, Cognitive impairment, and neuromuscular dysfunction. Data derived from the National Health and Nutrition Examination Survey (NHANES III) suggest that about one in 300 persons in the United States has Hypothyroidism there is a 4 – 5 % prevalence of Hypothyroidism in the developed world. The prevalence of Hypothyroidism in urban **India is 10.95 %**. A major portion of Hypothyroidism (approximately 3.47 %) remains undetected.

Various treatment protocols are applied in this disease with partial success. In a present clinical study, 30 patients with clinically proven Hypothyroidism were treated with *Kanchanar Gutika* to evaluate its efficacy. The Ingredients Of *Kanchanar Gutika* are *Bhibhitak* (*Terminalia Bellerica*), *Haritaki* (*Terminalia Chebula*), *Amalaki* (*Embllica Officinalis*), *Kanchanara* (*Bauhinia Variegata*), *Maricha* (*Piper Nigrum*), *Shunthi* (*Zinziber Officinalis*), *Pippali* (*Piper Longum*), *Guggul* (*Commiphora Mukul*) etc.

Ayurvediya nidanadi parameters and modern symptoms of Hypothyroidism were used as subjective parameters & investigation was used as objective parameters to assess the efficacy of the drug. Analysis was done and results were calculated statistically using the paired ‘t’ test. Results obtained are encouraging and indicate the efficacy of *Kanchanar Gutika* in the management of Hypothyroidism, exploring many aspects of this clinical entity.

Keywords: Hypothyroidism, Galaganda, *Kanchanar Gutika*

Introduction:

Hypothyroidism is the most common endocrine disorder observed all over the world in present time. It occurs about 7-8 times more frequently in females than males. In infants, symptoms do not appear till six months because enough hormone is present in mother’s milk. It affects the quality of life of individuals. The only treatment available is synthetic thyroxine tablets which patients had to take life-long.

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Agni is the unique concept of Ayurveda related to *Pachanas* or conversion, *Dhatupaka* of metabolism, etc. i.e. Various chemical reactions caused in the body. It is responsible for controlling each & every process of conversion. The normal, as well as abnormal function of

the thyroid gland, can be Correlated to the healthy & altered status of *Agni*. On reviewing the clinical presentation of Hypothyroidism from various sources, it is found that in Hypothyroidism, there is an abnormality of *Jathrangni & Dhatwagni* along, *Medovaha, Shukravaha & Manovaha srotas*. These factors should be addressed during the Ayurvedic management of Hypothyroidism.

Aims & Objectives:

Aim: -

Clinical study to evaluate the efficacy of *Kanchanar Gutika* in the management of *Galganda* w.r.t. Hypothyroidism.

Objective: -

- To study the aetiopathogenesis of Hypothyroidism in the light of Ayurvedic principles.
- To evaluate the efficacy of *Kanchanar Gutika* in the management of Hypothyroidism.
- To evolve a cost-effective remedy for Hypothyroidism

Ethical Clearance:

This clinical study was ethically cleared by the institutional ethical committee. The drugs used in the study were authenticated by *Dravyaguna and Rasashashtra* Dept. of D. Y. Patil School of Ayurveda, Nerul, Navi-Mumbai.

Samprapti Ghatakas Of Hypothyroidism:

(1) *Dosha Kapha–Avlambaka Kledaka Vata - Samana*

(2) *Dushya - Rasa Dhatu*

(3) *Agni Jathragni - Rasa Dhatvagni Bhutagni* mainly *Prithvi* and *Aapya Mahabhutagni*

(4) *Srotasa: Rasavaha Srotasa Manovaha Srotasa*

(5) *Srotodusti: Sanga, Vimarga Gamana*

(6) *Adhithana –Sarvana* (whole-body)

(7) *Udbhavsthana - Aamashaya*

(8) *Prasara - Rasayanies*

(9) *Rogamarga -Bahya*

(10) *Aama –Jathragnimandhyajanit Dhatvagnimandhyajanit*

(11) *Vyaktisthana –Sharira*

Materials & Methods

Kanchanar Gutika Yoga Ingredients:-

Drug	Rasa	Guna	Virya	Vipaka
Bhibhitak	Kashaya	Ruksha, Laghu	Ushna	Madhura
Haritaki	Pancharas (Lawanrahit)	Ruksha, Laghu	Ushna	Madhura
Amalaki	Pancharas (Lawanrahit)	Ruksha, Sheeta, Guru	Sheeta	Madhura
Kanchanar	Kashay	Ruksha, Laghu	Sheeta	Katu
Maricha	Katu	Laghu, Tikshan	Ushna	Katu
Guggul	Tikta,	Laghu, Ruksha Tikshan	Ushna	Katu
Shunthi	Katu	Laghu , Snigdha	Ushna	Madhura

Pippali	Katu	Laghu, Snigdha, Tikshna	Anushna Sheeta	Madhura
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Method

Showing Method of these study:

Research Place	D.Y. Patil School of Ayurveda Nerul, Navi Mumbai.
Sample size	30 patients
Medicine	Kanchanar Gutika
Dose	1 gms BD
Duration	3 Months
Kaal	Adhobhakta kala

Criteria for Selection of Patients:

Patients were selected from the OPD and IPD of the Department of Kayachikitsa, D.Y. Patil School of Ayurveda, Nerul, Navi Mumbai.

Inclusion Criteria:

Subjects fulfilling the following conditions were included:

- Under the age of 20-60 years.
- Patients who are ready to switch over the Ayurvedic medicine and sign the informed consent form.
- Patients who have already been diagnosed with Hypothyroidism and under Thyronorm [levothyroxine] medication but presenting with the diagnostic criteria are included.

Exclusion Criteria:

The following Subjects were excluded from the study:

- Patients who have undergone any type of thyroid surgery.
- Patients suffering from systemic diseases like cardiac disorders, diabetes mellitus, carcinomas, etc.
- Patients suffering from congenital Hypothyroidism and secondary Hypothyroidism.
- Pregnant women, hyperthyroidism, neoplasia, toxic goiter are excluded.

Criteria For Assessment -

Clinical assessment:

- The common symptoms like generalized pain, headache, puffiness of face, Anorexia, Constipation, Fatigability lethargy, Coarse Skin, Hoarseness of voice and Loss of hair are assigned for grading according to their severity as follows:

Observation	Grade
Complete relief	0
Presence of mild symptoms	1
Presence of moderate symptoms	2
Presence of severe symptoms	3

The assessment of each of the specific symptoms are done by assigning the score as follows:

1) **Oedema-** The score of edema is given on the basis of involvement of the affected area.

Observation	Grade
No edema	0
Oedema on lower / upper extremity	1
Oedema on both upper and lower extremities	2
Oedema on all over the body	3

(2) **Muscle cramps-** On the basis of the occurrence of muscle cramps in seven days, a score is given

Observation	Grade
Not present	0
Once a week	1
Twice / thrice in a week	2
Continuously present	3

(3) **Dry skin**

Observation	Grade
No dryness	0
Dryness after bath only	1
Dryness whole day but relieved by oil application	2
Dryness whole day but not relieved even after oil application	3

(4) **Excessive sleep** - The total hours of sleep in 24 hours will be noted and assigned score as following

Observation	Grade
HOURS/ DAY	0
8HOURS / DAY	1
10HOURS / DAY	2
MORE THAN 10 HOURS / DAY	3

5) **Loss of hair**

Observation	Grade
Absent	0
Hair fall on washing	1

Hair fall on combing	2
Hair fall on simple stretching	3

6) **Puffiness of face**

Observation	Grade
Absent	0
Occasional	1
Daily periorbital oedema /puffiness in the morning relieved in later part of day	2
Persistent	3

7) **Lethargy** –Lethargy will be assessed on the basis of piper fatigue scale (PFS)

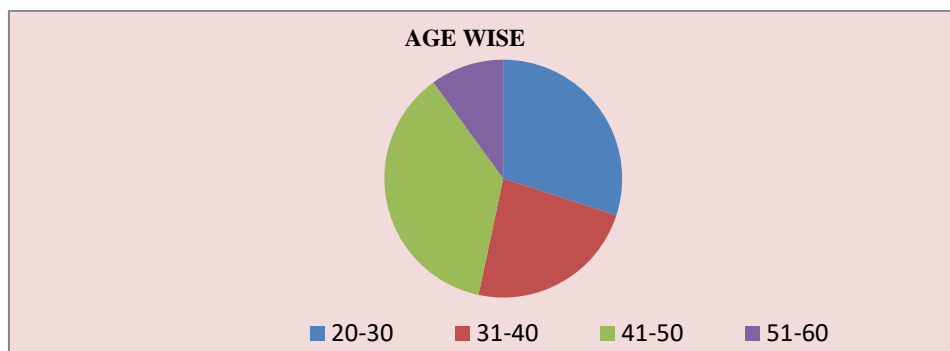
Observation	Grade
Doing work satisfactorily with proper vigor in time	0
Doing work without desire unsatisfactorily but in time	1
Doing work without desire unsatisfactorily with lot of mental pressure and not in time	2
Not starting any work in his /her own responsibility doing little work very slow	3
Does not have any initiation and does not want to work even after pressure	4

Observations & Results

Observations

Age wise Distribution of 30 patients of *Galganda* (hypothyroidism)

Age In Yrs	No. Of Patients	% Of Pts In Different Age Group
20 – 30	09	30
31 – 40	07	23.33
41 – 50	11	36.66
51 – 60	03	10



Gender wise Distribution of 30 patients of *Galganda* (hypothyroidism)

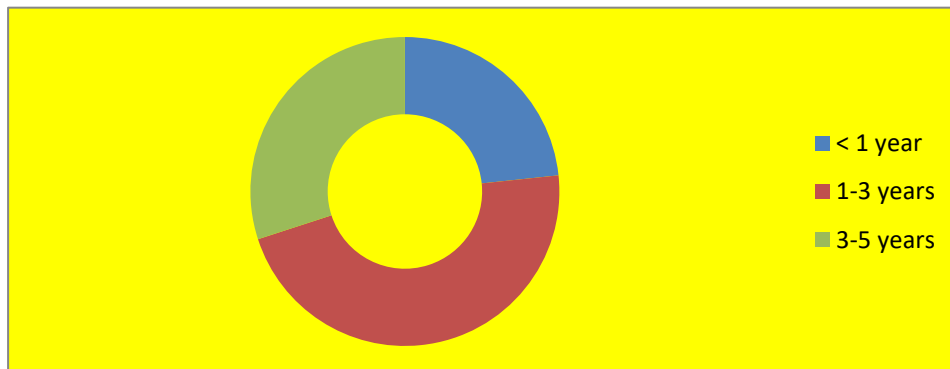
Gender Wise Distribution		
Sex	No. Of Patients	%
Female	20	66.66
Male	10	33.33



Results

Chronicity wise Distribution of 30 patients of *Galganda* (hypothyroidism)

Chronicity Wise Distribution		
Chronicity	No. Of Patients	%
< 1 Year	07	46.66
1-3 Years	14	30
3-5 Years	09	23.33



1) Wilcoxon Test:

Sr. No.	Variables	Bt	At	P	Result	%
1	Oedema	2.71	0.73	< 0.0001	Significant	73.06
2	Muscle cramps	2.62	0.9	< 0.0001	Significant	65.64

3	Dry Skin	2.59	0.73	< 0.0001	Significant	71.81
4	Puffiness Of Face	2.548	0.6	< 0.0001	Significant	76.37
5	Loss Of Hair	2.69	0.6	< 0.0001	Significant	77.69
6	Excessive Sleep	2.59	0.6	< 0.0001	Significant	76.83
7	Lethargy	3.405	0.467	< 0.0001	Significant	86.17

Tab Kanchanar Gutika provided highly significant relief in all the symptoms.

- P value of **Oedema** is <0.0001, hence the result is highly significant.
- P value of **Muscle cramps** is <0.001, hence result is highly significant.
- P value of **Dry skin** is <0.001, hence result is highly significant.
- P value of **Puffiness of face** is <0.001, hence result is highly significant.
- P value of **Loss of hair** is <0.001, hence result is highly significant.
- P value of **Excessive sleep** is <0.001, hence result is highly significant.
- P value of **Lethargy** is <0.001, hence result is highly significant.

2) PAIRED -T- TEST:

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Sr. No.	Variables	Bt	At	T	P	Result
1	Hb	11.9	11.4	4.15	< 0.0001	Significant
2	Rbs	137.36	130	2.853	0.004	Significant
3	Cholesterol	211.05	199.67	5.848	< 0.0001	Significant
4	T3	1.73	1.68	0.3446	0.3664	Not Significant
5	T4	7.258	7.44	0.8544	0.200	Not Significant
6	Tsh	6.322	4.64	7.866	< 0.0001	Significant
7	Sr. Creatinine	0.9286	0.91	1.095	0.1413	Not Significant

- P value of **Hb** is < 0.0001 hence result is **significant**.
- P value of **RBS** is 0.004 hence result is **significant**.
- P value of **Cholesterol** is < 0.0001 hence result is **significant**
- P value of **T3** is 0.3664 which is > 0.005 hence result is **non- significant**.
- P value of **T4** is 0.200 which is > 0.005 hence result is **non- significant**.
- P value of **TSH** is < 0.0001 hence result is **significant**.

- P value of **Sr. Creatinine** is 0.1413 which is > 0.005 hence result is **non-significant**

Result:

- According to statistical analysis, significant results were observed in the following parameters are Oedema, Muscle Cramps, Dry Skin, Puffiness of Face, Loss of Hair, Lethargy Excessive Sleep, Forgetfulness.
- The significant value ($p < 0.0001$) observed in Blood Investigations, i.e., Hb, RBS, Cholesterol, and TSH,
- And non-significant value ($p > 0.005$) observed in Blood Investigations, i.e, T3, T4, and Sr. Creatinine.
- Thus, it can be concluded that *Kanchanar Gutika* plays an effective role in the management of Hypothyroidism without any side effects, which is concluded by the above blood investigations.

Discussion

Disorders of the thyroid gland are old as the history of mankind. Even now nearly 200 million population in the world is suffering from thyroid disorders. Hypothyroidism is a common thyroid disorder which is resulting from a deficiency of thyroid hormones.

Hypothyroidism as such is not mentioned in Ayurveda, but with the help of its clinical presentation and *DoshaDushya-Siddhanta* of Ayurveda, it can be very well understood and managed. In Ayurveda, the disorders of the thyroid gland are described under the title of *Galganda*. *Sushruta* has mentioned that it appears *Muskavata* in *Gala* which means it hangs like a scrotum in the neck region (Su. Ni. 11) which indicates the two lobes of the thyroid gland. The signs and symptoms of hypothyroidism mentioned in modern medicine show that *Kapha Dosha* plays a major role in this disease, secondly, the involvement of *Vata dosha* is also there. From the *Dahtu* point of view, it can be said that mainly the *Dushti* of *Rasadhatu* is seen in hypothyroidism. If we see the *Nanatatmaja Kapha Roga* (Ch. Su. 20) and *Rasaja Vikara* (Ch. Su. 28), most of them are present as a symptom of hypothyroidism. *Dhatvagni Madhya* is also a major feature of this disease. On the basis of all these points, we can compare hypothyroidism with *Kaphaja Galganda*. It satisfied both, the involvement of the thyroid gland as well as the symptom complex of hypothyroidism.

There is no direct mention of the Thyroid gland and Hypothyroidism in Ayurveda. However, a disease named *Galganda*, characterized by neck swelling is well known. *Aacharya Charaka* has included it under *20 Shleshma Vikara*. *Aacharya Sushruta* has mentioned the seat of *Galganda* as *Rohini Twacha*, the sixth layer of skin. *Charaka* described it as a solitary swelling while *Sushruta* has mentioned it as two encapsulated, big or small swelling, hanging like a scrotum, in the anterior angle of the neck. *Bhela* describes *Shleepada* and *Galganda* are more common in *Prachya Desha* (eastern parts of the country) and that of consumption of fish predominantly are liable to develop *Galganda*. *Harita* has described the role of *Dushtambu* (contaminated water) and *Krimi Dosha* (infections) in the precipitation of disease. *Kashyapa* has further added that regions that are cold, damp, with densely grown trees, water stagnation, and heavy rains may be prone for *Galganda*. Although these facts are mentioned centuries ago, it is still an accepted fact that environmental factors, especially iodine, play an important role in the functioning of thyroid gland. From the above description, *Galganda* can be correlated with the Simple Goitre, the non-inflammatory, non – neoplastic condition of thyroid gland. It is observed both in hypothyroidism and hyperthyroidism. Any imbalance in iodine metabolism, either too much or too little iodine can result in the development of goiter. Goiter is a localized condition but hypothyroidism is related to many systems of the body.

The comparative study shows that almost all symptoms of Hypothyroidism can be incorporated in *Ama -Lakshana*. The causes of *Aama Dosha* are mainly dietary. It is observed

that *Nidana Sevana* of *Aama Dosha* further aggravates the symptoms of Hypothyroidism. *Nidana Parivarjana* is the basic treatment of any disease in Ayurveda. The *Nidana Parivarjana* of *Aama Dosha* gives symptomatic relief and restrains further advancement of the disease. The *Deepana – Pachana* therapy of *Aama Dosha* strengthens *Jatharagni* and in turn regularizes *Bhootagni* and *Dhatvagni*. Thus, Ayurveda therapy not only gives symptomatic relief but also metabolism at the cellular level is kept in check. So, it can be concluded that the treatment of *Aama Dosha* can be useful in Hypothyroidism.

The thyroid hormone economy denotes the processes involved in the synthesis of hormones in the thyroid gland, their transport in the circulation, their action and metabolism in the peripheral tissues, and its regulatory mechanism that maintain a normal supply of thyroid hormones. By evaluating the pathophysiology of the thyroid gland, it becomes evident that the main economy which involves synthesis, its transport, action, and metabolism, and regulatory processes triggered by hypothalamic response of TSH in the brain, of them, can get disturbed. Hence, both central activity and peripheral gland functioning are the main components getting affected. Stress has got both positive and negative effects. The imbalance between these two affect psycho-neurological imbalances, reduce immune response and active oxygen metabolism ultimately causing dys-hormony in the dynamic balance of homeostasis in the *sharira* (physical component i.e. *Tridosha*), *satva* (mental components i.e. *raja & tama*) *avayava* (organs, tissues, and *srotasa*), *indriyas* (sense organs) and also to *atma* (life principles). Today the increasing trend of hypothyroidism is alarming. As per the concern of Ayurveda, Hormonal replacement is not possible through other drugs. But keeping the principle of vitiation of Agni in mind, the wholesome activity of the thyroid gland may be brought to a cognizable by means of Ayurvedic drugs.

Conclusion

At the verge of completion of this study final conclusion drawn on the basis of deductive reasoning of data obtained from this clinical trial are:

- Shedding light on the symptomatology of the disease on the basis of Ayurvedic fundamentals it becomes evident that the *Kapha Dosha*, *Rasa dhatu* plays a major role in the pathogenesis
- Observation highlighted that major etiological factors found responsible for the occurrence of the disease in this study were faulty dietary habits & stress.
- Results were not found significant in S. T3, S.T4 levels after completion of the course.
- Results were found significant in S. TSH levels after completion of the course.
- During the follow-up study, patients complained of an increase in grade of symptoms after discontinuation of therapy. It shows that therapy should be administered for a longer duration and then the analysis should be done.
- Significant results on various symptoms elucidate the effectiveness of therapies in combating probable *samprapti* of this disease.
- Probably, 12 weeks is not a sufficient duration to cure *aama* and *agnimandya* at that level. Results could have been more effective if the study would have been done for a longer duration. A longer duration could not be kept in the present study due to the limitation of time.

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