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

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ABSTRACT

Hypothyroidism is defined as failure of the Thyroid Gland to produce sufficient Thyroid hormone to meet the metabolic demands of the body. The prevalence of Hypothyroidism in urban India is 10.95%. Major portion of Hypothyroidism (approximately 3.47%) remain undetected. Various treatment protocols are applied in this disease with partial success. In present clinical study, 30 patients of 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* (*Emblica Officinalis*), *Kanchanara* (*Bauhinia Variegate*), *Maricha* (*Piper Nigrum*), *Shunthi* (*Zinziber Officinalis*), *Pippali* (*Piper Longum*), *Guggul* (*Commiphora Mukul*) etc.^[1] *Ayurvediya Nidanadi* parameters and modern symtoms of Hypothyroidism were used as a subjective parameters & investigation was used as objective parameters to assess the efficacy of the drug. Analysis was done and results were calculated statistically using 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.^[1]

Key words: 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 lifelong. [2]

Hypothyroidism is defined as failure of the Thyroid

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Gland to produce sufficient Thyroid hormone to meet the metabolic demands of the body. Untreated Hypothyroidism can contribute to Hypertension, Dyslipidemia, [3] 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 4 - 5% prevalence of Hypothyroidism in developed world. The prevalence of Hypothyroidism in urban India is 10.95%. Major portion of Hypothyroidism (approximately 3.47 %) remain undetected. Prevalence in Mumbai is approximate 9.5%. Incidence of hypothyroidism is more in females & elderly persons.[2]

Agni is the unique concept of Ayurveda related to *Pachanas* or conversion, *Dhatupaka*^[5] of metabolism etc. i.e. Various chemical reactions causing in the body. It is responsible for controlling each and every process of conversion. The normal as well as abnormal function of thyroid gland can be Correlated to healthy and altered status of *Agni*. On reviewing

the clinical presentation of Hypothyroidism from various sources, it is found that in Hypothyroidism, there is abnormality^[6] of *Jathrangni* and *Dhatwagni* along, *Medovaha*, *Sukravaha* and *Manovaha Srotas*. These factors should be addressed during Ayurvedic management of Hypothyroidism.^[3]

AIM

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

OBJECTIVE

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

Ethical Clearance

This clinical study was ethically cleared by 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^[4,7]

- 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. Adhisthana- Sarvana (whole body)
- 7. Udbhavsthana- Aamashaya
- 8. Prasara-Rasayanies
- 9. Rogamarga-Bahya
- 10. Aama- Jathragni Mandhyajanit Dhatvagni Mandhyajanit

11. Vyaktisthana- Sharira

MATERIALS AND METHODS

SOP of preparation of Kanchanara Gutika^[5]

Get 3 parts of *Triphala* (having mixture of equal quantity of its ingredients), 6 parts of *Vyosa* (also having equal quantity of its ingredients) and bark of *Kanchanara* (18 parts). Combine all these materials together and powder them. Take *Guggulu* equivalent to the combined weight of all the materials (i.e. 36 parts) and dissolve it in decoction of *Triphala*. subsequently, take honey 10 times greater than *Triphala* (i.e. 30 parts) and collect all the materials in a mortar. When the compound is saturated due to continuous triturating, prepare pills measuring 250gm. Each and preserve them in glass bottles after drying the same. This medicine is known as *Kanchanara Gutika* [5] and is capable of curing all types of *Gandamal, Galaganda, Nadivrana* and the like.

Table 1: Ingredients of *Kanchanara Gutika*^[6]

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	Kashaya	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 the 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
Kala	Adhobhakta Kala

Criteria for Selection of Patients

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

Inclusion Criteria^[10]

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 are already diagnosed as 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 under gone 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 goitre are excluded.

Criteria for assessment^[9]

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 specific symptoms are done by assigned the score as follows:

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

Observation	Grade
No oedema	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 occurrence of muscle cramps in seven days, score is given;

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

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Continuously present	3
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
8 hours / Day	1
10 hours / 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 withproper 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 not want to work even after pressure	4

OBSERVATIONS AND RESULTS

Table 1: Age wise Distribution of 30 patients of *Galganda* (hypothyroidism)

Age wise distributon	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		

Table 2: Gender wise Distribution of 30 patients of *Galganda* (hypothyroidism)

Gender wise distribution	No. of patients	%
Female	20	66.66
Male	10	33.33

Table 3: Chronicity wise Distribution of 30 patients of *Galganda* (hypothyroidism)

Chronicity wise distribution	No. of patients	%
< 1 year	07	46.66
1-3 years	14	30
3-5 years	09	23.33

Table 4: Effect of therapy on subjective parameters.

SN	Variabl es	В	Т	4	AT	р	Result	%
1.	Oedem a	2.71		(0.73	< 0.000 1	Significa nt	73.0 6
2.	Muscle cramps	2.62		(0.9	< 0.000 1	Significa nt	65.6 4
3.	Dry skin	2.59		(0.73	< 0.000 1	Significa nt	71.8 1
4.	Puffine ss of face	2.548		(0.6	< 0.000 1	Significa nt	76.3 7
5.	Loss of hair	2.69		0.6		< 0.000 1	Significa nt	77.6 9
6.	Excessi ve sleep	2.59		0.6		< 0.000 1	Significa nt	76.8 3
7.	Lethargy 3.40 5			0.46 7	< 0.000 1	Significa nt	86.1 7	

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

 P value of Oedema is <0.0001, hence result is highly significant.

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- 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.

Table 5: Effect of therapy on objective parameters.

S N	Variables	ВТ	AT	t	р	Result
1.	НВ	11.9	11.4	4.15	< 0.000 1	Significa nt
2.	RBS	137.3 6	130	2.853	0.004	Significa nt
3.	Cholester ol	211.0 5	199.6 7	5.848	< 0.000 1	Significa nt
4.	Т3	1.73	1.68	0.344 6	0.366 4	Not Significa nt
5.	Т4	7.258	7.44	0.854 4	0.200	Not Significa nt
6.	TSH	6.322	4.64	7.866	< 0.000 1	Significa nt
7.	Sr. Creatinin e	0.928 6	0.91	1.095	0.141 3	Not Significa nt

 P value of Hb is < 0.0001, hence result is significant.

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- 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 issignificant.
- 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 following parameters are Oedema, Muscle Cramps, Dry Skin, Puffiness of Face, Loss of Hair, Lethargy Excessive Sleep, Forgetfulness and 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 effective role in the management of Hypothyroidism without any side-effects, which is concluded by the above blood investigations.

DISCUSSION

Disorders of thyroid gland is old as the history of mankind. Even now nearly 200 million population of the world is suffering from the 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 *Dosha Dushya Siddhanta* of Ayurveda it can be very well understood and managed. In Ayurveda the disorders of thyroid gland are described under the title of *Galganda*. Sushruta has mentioned that it appears *Muskavata* in *Gala* which means it hang like a scrotum in neck region (Su. Ni. 11) which indicates towards the two lobes of thyroid gland. The signs and symptoms of

hypothyroidism mentioned in modern medicine show that *Kapha Dosha* play 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 *Rasa Dhatu* is seen inhypothyroidism. 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 in this disease. On the basis of all these points we can compare the hypothyroidism with *Kaphaja Galganda*. It satisfied both, involvement of thyroid gland as well as symptom complex of hypothyroidism.

There is no direct mention of Thyroid gland and Hypothyroidism in Ayurveda. However, a disease named Galganda, characterised 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 scrotum, in the anterior angle of neck. Bhela describes Shleepada and Galganda are more common in Prachya Desha (eastern parts of 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, plays an important role in the functioning of thyroid gland. From the above description, Galganda can be correlated with the Simple Goitre, the noninflammatory, non-neoplastic condition of thyroid gland. It is observed both in hypothyroidism and hyperthyroidism. Any imbalance metabolism, either too much or too little iodine can result in development of goitre. Goitre is a localised condition but hypothyroidism is related to many systems of the body. [5]

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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 disease.^[9]

The *Deepana - Pachana* therapy of *Aama Dosha* strengthens *Jatharagni* and in turn regularizes *Bhootagni* and *Dhatvagni*. Thus, the Ayurveda therapy not only gives symptomatic relief but also metabolism at the cellular level is kept into check. So, it can be concluded that the treatment of *Aama Dosha* can be useful in Hypothyroidism.

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 anormal supply of thyroid hormones. By evaluating patho-physiology of thyroidgland, it becomes evident that the main economy which involves synthesis, itstransport, action and metabolism and regulatory processes triggered by hypothalamic response of TSH in brain, any of them can get disturbed. Hence, both central activity and peripheral gland functioning are the main component sgettingaffected. Stress has got both positive and negative effect. Imbalance between thesetwo-affect psycho-neurological imbalances, reduce immune response and active oxygen metabolism ultimately causing dyshormony in dynamic balance of homeostasis in the Sharira (physical component i.e. Tridosha), Satva (mental components i.e. Raja and Tama) Avayava (organs, tissues and Srotasa), Indriyas (sense organs) and also to Atma (lifeprinciples). Today increasing trend of hypothyroidism is alarming. As per concern of Ayurveda, Hormonal replacement is not possible through other drugs. But keeping the principle of vitiation of Agni in mind, wholesome activity of thyroid gland may be brought to a congnigible by means of Ayurvedic drugs. [2]

CONCLUSION

On the basis of the study following conclusions can be drawn. Thyroid gland is essential for metabolism in the body. Agni is entity that brings about all kind of transformations in the body according to Ayurveda. Agnimandya is precursor factor of all the diseases resulting in Ama formation. Symptoms of Aama and Hypothyroidism are almost similar. Although the disease hypothyroidism is not described in classical Ayurvedic texts. Based on its clinical presentation its Samprapti (pathogenesis) can be understood as follows; Nidana-Santarpanottha, Dosha Kapha, Vata, Dushya-Rasa, Meda, Mamsa, Asthi, Majja, Sukra, Samuththana-Amasaya, Adhisthana-Sarva Shareera, Srotodushti Sanga, Rogamarga: Abhyantara (Kostha), Srotodusti: Sanga, Agni Mandya: Ama Jathar Agni Mandya Janita, Ama Rasa-Rakta Dhatvagni Jaita. During the treatment of hypothyroidism these pathogenetic factors has to be targeted with special attention to strength of body, mind and Dosha. Observation highlighted that major etiological factors found responsible in the occurrence of the disease in this study was faulty dietary habits and 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 follow up study, patients complained increase in grade of symptoms discontinuation of therapy. It shows that therapy should be administered for longer duration and then analysis should be done. Significant results on various symptoms elucidate effectiveness of therapies in combating probable Samprapti of this disease. Probably, 12 weeks is not sufficient duration to cure Aama and Agnimandya at Dhatu level. Results could have been more effective if study would have been done for longer duration. Longer duration could not kept in the present study due to limitation of time.

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