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# A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF KANCHANARA GUGGULU AND GANDAMALAKANDANA RASA ALONG WITH NICHULADI LEPA IN THE MANAGEMENT OF GALAGANDA W.S.R. TO THYROTOXICOSIS

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## ABSTRACT

Patients with thyroid diseases suffer either from hyper functioning or hypo functioning of the gland, commonly referred as Hyperthyroidism and Hypothyroidism respectively. About 1-2% of adult population is known to suffer from thyroid disorders. According to 1999 World Health Assembly report about 1.5 billion persons in more than 110 countries are threatened with thyroid disorders. Prevalent data indicates that Thyrotoxicosis is more frequent in females than males, seen in the ratio of 9:1 and effects the age between 20-50 years. Gandamalakandana Rasa and Nichuladi lepa has the properties like Pittagna, Shothahara,Madhura rasa, Ushna veerya and Vata Shamaka its 0ver all efficacy is compared with Kanchanara guggulu which is all ready established. In this study, 40 patients suffering from classical features of Thyrotoxicosis as mentioned in the inclusion criteria were selected and assigned into 2 groups of

20 patients each. Group A as Trail group, was treated with Gandamalakandana Rasa and Nichuladi lepa for 45 days and Group B was treated with Kanchanara guggulu for 45 days. Better clinical therapeutic efficacy was found in patients of Gandamalakandana Rasa and Nichuladi lepa compared with Kanchanara guggulu because the earlier was both given internally and external application. Overall response was statistically similar in both the Groups with 'P' value of 0.422.

**Key words** - Thyrotoxicosis, Goiter, Gandamalakandana Rasa, Kanchanara guggulu

## INTRODUCTION

Earliest reference regarding Galaganda is available in Sushruta samhita. The disease is dealt in detail with its samprapti, lakshana and chikitsa. Even surgical excision of the gland has been explained by Acharya Sushruta. A critical analysis on the disease mentioned in Ayurvedic classics, resembles Thyrotoxicosis of contemporary science. Thyroid problems are among the most common endocrine disorders presently seen worldwide. About 1-2% of adult population is known to suffer from thyroid disorders. According to 1999 World Health Assembly report about 1.5 billion persons in more than 110 countries are threatened with thyroid disorders.

Hyperthyroidism is the result of excess production and delivery of thyroid Hormone into circulating blood often referred to as Thyrotoxicosis. In the light of Modern era Thyrotoxicosis is caused due to Auto immune mediated antibody antigen reaction.

The annual incidence of Thyrotoxicosis varied from 9.7 to 49.2 per 1 lakh in a Collaborative study in 12 towns in England and Whales. Prevalent data indicates that Thyrotoxicosis is more frequent in females than males, seen in the ratio of 9:1 and effects the age between 20-50 years.

In the conventional system of medicine, patients are treated with Antithyroid drugs for about 12 – 24 months, where prolonged remissions of the illness are generally observed and the patients may develop hypothyroidism. Side effects like nausea, allergic reactions, decrease in WBC etc are seen making the person vulnerable for infections. With Radioactive iodine 40 – 70% of the patients develop hypothyroidism which may require Thyroxine replacement therapy for rest of their life; hence life time follow up will be required. Though the surgical removal of the gland by Thyroidectomy is practiced and has a better cure, some degree of hypothyroidism can occur after surgery and also complications in the form of damage to the Parathyroid gland and paralysis of the vocal cords will be seen.

There are many preparations with Herbal and Herbo mineral contents, Asavarishtas, Ghritas and different yogas mentioned in the classics for effective management of Galaganda. Also local applications in the form of lepas have been mentioned for the same. The importance of Panchakarma like Vamana etc. has

been mentioned and a special mention about Shastra chikitsa and Anushastra chikitsa has also been explained by the Acharyas.

Thus with such a wide pool of knowledge available in Ayurveda, and the need of the hour where all system of medicines are coming together to find a definite result with an holistic approach, an attempt has been made to tackle the disease with an efficacious treatment combination of a Gandamalakandana Rasa, a shamanaushadi and Nichuladi lepa which are based on Ayurvedic references available in the classics as this can be easily administered to the patient, is economical and free from side effects. Also to avoid the above said complications of modern medicine & to provide better relief.

In order to evaluate this method of treatment another method of treatment with Kanchanara Guggulu with success rate of 70% is taken as an established study group with reference from previous dissertation.

**OBJECTIVES OF THE STUDY:**

- To understand the aetiopathogenisis of Thyrotoxicosis in the light of Ayurvedic principles.
- To evaluate the efficacy of Gandamalakandana Rasa and Nichuladi lepa in the management of Galaganda w.s.r. to Thyrotoxicosis.
- To evaluate the efficacy of Kanchanara Guggulu in the management of Galaganda w.s.r. to Thyrotoxicosis.

## METHODOLOGY

The study was conducted at Government Ayurvedic Medical College and SJIIM hospital, Bengaluru during November 2011 to April 2013. In this study the management of Thyrotoxicosis by Kanchanara Guggulu has been considered as established study with reference to the previous dissertations. Success rate of 70% was seen with the same.

**Source of data**

The patients with classical features of Thyrotoxicosis attending the OPD and IPD of SJIIM hospital, Bengaluru were selected for the present clinical study.

**Method of collection of data**

40 patients suffering from classical features of Thyrotoxicosis as mentioned in the inclusion criteria were selected for the study.

**Criteria for selection of cases Inclusion criteria**

- Patients diagnosed with classical signs and symptoms of Thyrotoxicosis with enlarged thyroid gland along with the chronicity of symptoms less than 12 months namely Fatigue, Increased appetite, Hyper defecation, Increased sweating, Heat intolerance, Palpitation, Insomnia, Tremors, Weight loss.
- Abnormal serum levels namely increased T3, T4 and reduced TSH levels.

**Exclusion criteria**

- Patients undergone Thyroid surgery.
- Patients associated with Congenital and Secondary Thyrotoxicosis, Multi Nodular Goitre, Adenomas, Sub Acute Thyroiditis, advanced condition of Exopthalmus, Dermopathy, Hypothyroidism and Neoplasia
- Patients suffering from other systemic diseases.

**Study design**

A total of 40 patients suffering from Thyrotoxicosis those fulfilling inclusion criteria were selected for the study and randomly divided into two groups of 20 patients each as Group A & Group B.

Table No.1 showing the treatment pattern in both the groups

| **Groups** | **Chikitsa** | **Prayoga** | **Avadhi** |
|---|---|---|---|
| Group A | Gandamalakandana Rasa along with<br>Nichuladi lepa | 250mg t.i.d<br>Once daily | 45 days<br>45 days |
| Group B | Kanchanara Guggulu | 250mg t.i.d | 45 days |

**PROCEDURE**

**GROUP A**

Patient was made to lie in supine position with neck extended. The anterior part of neck was cleaned with cotton swab dipped in lukewarm water and moped with a clean towel. Nichuladi lepa choorna was taken in sufficient quantity in a bowl and mixed with lukewarm water to bring about consistency of paste. The same was applied over Thyroid area with a spatula in Pratiloma gati with the thickness of Ardra mahisha charma.

The lepa was allowed to dry after application. Later dried lepa was washed with lukewarm water and moped. The procedure was done once daily for a period of 45 days.

One Gandamalakandana Rasa vati, 250mg was taken internally in the morning, afternoon and night after food for a period of 45 days with warm water.

In cases where severe complications were seen during the period of study, the same were referred to higher centre for the needful and were excluded from the study and in such cases total number of cases excluded were replaced by new one.

**GROUP B**

One Kanchanara Guggulu vati, 250mg was taken internally in the morning, afternoon and night after food for a period of 45 days with warm water.

In cases were severe complications were seen during the period of study the same were referred to higher centre for the needful and were excluded from the study in such cases total number of cases excluded were replaced by new one.

**Laboratory Investigation**

Following investigations were carried out in all the patients of Group A & Group B before and after treatment.

Serum $T_3$, $T_4$ and TSH levels

**Observation period**

The observations regarding the parameters before treatment and changes after treatment were noted and the same were recorded in the proforma of case sheet prepared for the study.

**Assessment criteria**

The results were evaluated by the following subjective & objective parameters.

**Subjective Parameters**

Table No.2 showing the Subjective Parameters

| Sl. No | Parameters | Grading |
|---|---|---|
| 1 | Fatigue | Present : 1 |
| | | Absent : 0 |
| 2 | Increased Appetite | Present : 1 |
| | | Absent : 0 |
| 3 | Hyper defecation | Present : 1 |
| | | Absent : 0 |
| 4 | Increased sweating | Present : 1 |
| | | Absent : 0 |
| 5 | Heat intolerance | Present : 1 |
| | | Absent : 0 |
| 6 | Palpitation | Present : 1 |
| | | Absent : 0 |
| 7 | Insomnia | Present : 1 |
| | | Absent : 0 |
| 8 | Tremors | Present : 1 |
| | | Absent : 0 |

**Objective Parameters**

Table No.3 showing the Objective Parameters

| Sl. No. | Parameters | Units | Before treatment | After treatment |
|---|---|---|---|---|
| 1 | Weight | kgs | | |
| 2 | Thyroidprofile: | | | |
| | T3 | ng/dl | | |
| | T4 | µg/dl | | |
| | TSH | µIU/ml | | |
| 3 | Enlarged thyroid gland | Grade | | |

**Enlarged thyroid gland (Goitre)**

Grade 0: no goitre presence is found (the thyroid is impalpable and invisible)

Grade 1: neck thickening is present in case of enlarged thyroid, palpable, however not visible in normal position of neck. The thickened mass moves upwards during swallowing, grade 1 includes also nodular goitre if thyroid enlargement remains invisible.

Grade 2: neck swelling, visible when neck is in normal position, corresponding to enlarged thyroid found in palpation.

FOLLOW UP PERIOD

In cases of complete relief, a period of 45 days was fixed to observe the possible recurrence of signs and symptom and the same were recorded in the proforma of case sheet.


Photo showing requirements of lepana karma

## RESULTS

### Subjective parameters:

Table No.4 showing the comparative evaluation of clinical parameters in two groups studied

Showing result on Subjective parameters

| Variables | Group | Before treatment (n=20) | During treatment (n=20) | After treatment (n=20) | % change | P value |
|---|---|---|---|---|---|---|
| Fatigue | Group A | 20(100%) | 17(85%) | 13(65%) | 35.0 | 0.111 |
| | Group B | 20(100.0%) | 17(85.0%) | 14(70.0%) | 30.0 | 0.152 |
| | P value | 1.000 | 1.000 | 0.736 | - | - |
| Increased Appetite | Group A | 20(100%) | 16(80%) | 11(55%) | 45.0 | 0.049* |
| | Group B | 20(100.0%) | 16(80.0%) | 12(60.0%) | 40.0 | 0.076+ |
| | P value | 1.000 | 1.000 | 0.749 | - | - |
| Hyper Defecation | Group A | 10(50%) | 10(50%) | 9(45%) | 5.0 | 0.411 |
| | Group B | 15(75.0%) | 15(75.0%) | 14(70.0%) | 5.0 | 0.427 |
| | P value | 0.191 | 0.102 | 0.110 | - | - |
| Increased Sweating | Group A | 19(95%) | 15(75%) | 11(55%) | 40.0 | 0.069+ |
| | Group B | 17(85.0%) | 15(75.0%) | 10(50.0%) | 35.0 | 0.087+ |
| | P value | 0.605 | 1.000 | 1.000 | - | - |
| Heat Intolerance | Group A | 16(80%) | 12(60%) | 9(45%) | 35.0 | 0.078+ |
| | Group B | 14(70.0%) | 13(65.0%) | 8(40.0%) | 30.0 | 0.099+ |
| | P value | 0.716 | 1.000 | 1.000 | - | - |
| Palpitation | Group A | 18(90%) | 13(65%) | 9(45%) | 45.0 | 0.038* |
| | Group B | 17(85.0%) | 16(80.0%) | 8(40.0%) | 40.0 | 0.032* |
| | P value | 1.000 | 0.288 | 0.749 | - | - |
| Insomnia | Group A | 18(90%) | 15(75%) | 10(50%) | 40.0 | 0.063+ |
| | Group B | 16(85.0%) | 15(75.0%) | 9(45.0%) | 40.0 | 0.055+ |
| | P value | 0.661 | 1.000 | 0.752 | - | - |
| Tremors | Group A | 17(85%) | 14(70%) | 9(45%) | 40.0 | 0.055+ |
| | Group B | 15(75.0%) | 16(80.0%) | 8(40.0%) | 35.0 | 0.069+ |
| | P value | 0.695 | 0.465 | 0.749 | - | - |

P values within each group is obtained using the Paired proportion test, for Pre and Post analysis

**Objective parameters:**

Table No.5 showing the comparative evaluation of objective variables in two groups in pre and post assessment

| Variables | BT | AT | Difference | SD | SE | t value | P value |
|---|---|---|---|---|---|---|---|
| Body weight | | | | | | | |
| • Group A | 49.45±5.82 | 49.85±5.92 | 0.40 | 0.68 | 0.15 | 2.63 | 0.017* |
| • Group B | 49.05±8.80 | 49.20±8.58 | 0.150 | 0.88 | 0.19 | 0.767 | 0.453 |
| • P value | 0.866 | 0.782 | - | - | - | - | - |
| T3 | | | | | | | |
| • Group A | 196.78±32.47 | 192.81±35.27 | 3.97 | 9.25 | 2.07 | 3.97 | 0.070+ |
| • Group B | 196.55±29.34 | 194.71±27.66 | 1.84 | 16.32 | 3.65 | 0.50 | 0.621 |
| • P value | 0.981 | 0.650 | - | - | - | - | - |
| T4 | | | | | | | |
| • Group A | 13.33±1.82 | 12.10±1.38 | 1.23 | 0.79 | 0.18 | 6.88 | <0.001** |
| • Group B | 12.90±1.38 | 12.58±1.37 | 0.33 | 1.08 | 0.24 | 1.35 | 0.194 |
| • P value | 0.410 | 0.276 | - | - | - | - | - |
| TSH | | | | | | | |
| • Group A | 0.24±0.11 | 0.49±0.54 | 0.25 | 0.48 | 0.11 | 2.34 | 0.030* |
| • Group B | 0.26±0.13 | 0.47±0.32 | 0.22 | 0.32 | 0.07 | 2.98 | 0.008** |
| • P value | 0.639 | 0.698 | - | - | - | - | - |

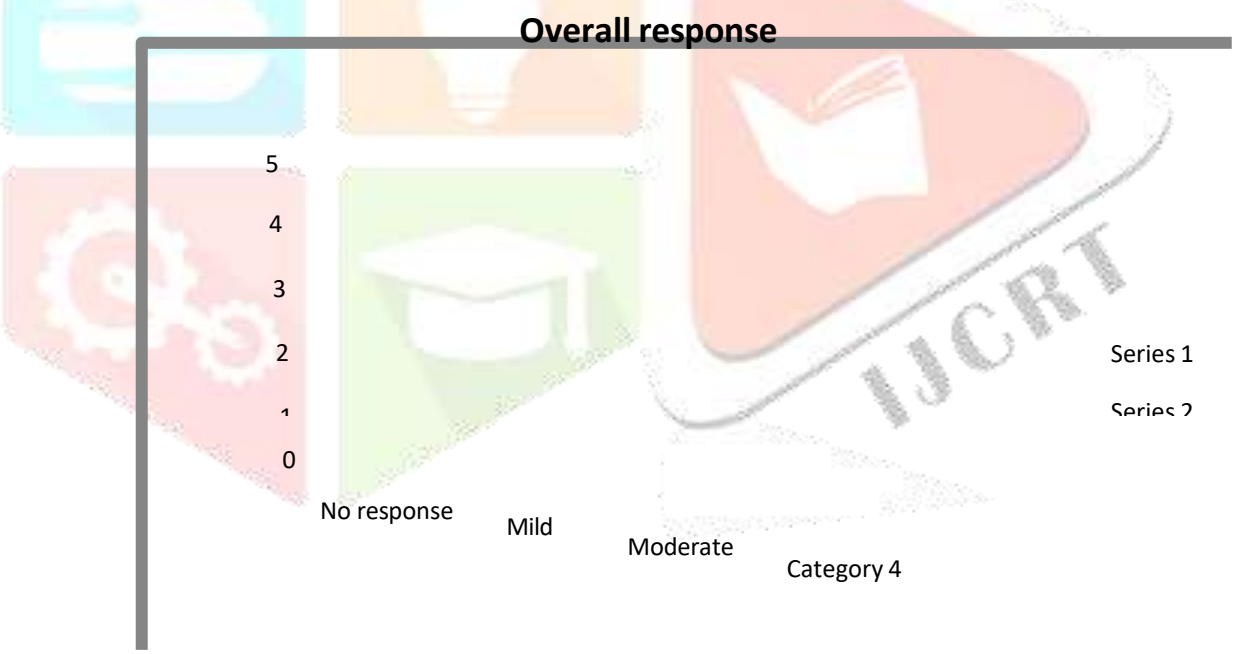
Table No.6 showing the comparative evaluation of enlarged thyroid gland in two groups in pre and post assessment

| Enlarged thyroid gland | BT (n=20) | AT (n=20) | % change |
|---|---|---|---|
| Group A | | | |
| • 1 | 7(35.0%) | 7(35.0%) | 0.0 |
| • 2 | 13(65.0%) | 13(65.0%) | 0.0 |
| Group B | | | |
| • 1 | 7(35.0%) | 7(35.0%) | 0.0 |
| • 2 | 13(65.0%) | 13(65.0%) | 0.0 |
| P value | 1.000 | 1.000 | - |

**Overall response:**

Table No.7 showing the assessment of overall response (based on 11 parameters)

| Overall Response | Group A | | Group B | |
|---|---|---|---|---|
| | No | % | No | % |
| No Response | 1 | 5.0 | 2 | 10.0 |
| Mild Response (<20% improvement) | 7 | 35.0 | 8 | 40.0 |
| Moderate Response (20-50% Improvement) | 9 | 45.0 | 7 | 35.0 |
| Marked response (>50% Improvement) | 3 | 15.0 | 3 | 15.0 |
| Total | 20 | 100.0 | 20 | 100.0 |
| Inference | Distribution of overall response is statistically similar in two groups with P=0.422 | | | |




## DISCUSSION

**Discussion on Probable mode of action of Nichuladi lepa**:

Galaganda is a bahyarogamargagata vyadhi, its adhisthana being sixth layer of twacha i.e. Rohini. Lepa is one among bahiparimarjana chikitsa and is an adhya upakkrama used in akshata shopha like Galaganda. Morbid doshas situated in twak and mamsadi dhatus are probably removed by application of Lepa by Doshashamana and Shodhana. Vata Shleshma hara properties of Lepa may help in mitigating the swellings of recent origin.

The transfer of the molecule of drug is expected to take place by trans dermal drug delivery system. When applied, the drugs get absorbed through skin in hair roots and enter the capillaries and are delivered into the blood stream. In Thyrotoxicosis hyper functioning and hypertrophy of gland is seen, drugs used may counteract both the pathologies.

Nichuladi lepa churna has a combination of Nichula, Shigru, Dashamula .Owing to their laghu guna and ushna veerya they may help in delivering the drug via blood stream.

Hyper functioning of gland may be correlated to hyperactivity of Vata dosha and contents of lepa churna are mainly Vatahara and Vishagna. Kaphahara and Shotahara properties of drugs may be attributed to probable reduction in Hypertrophy of gland i.e. reduction in the size of enlarged thyroid gland.

**Discussion on Probable mode of action of Gandamalakandana Rasa:**

The ingredients of Gandamalakandana rasa are Kanchanara, Guggulu, Trikatu, Saindhava, Kajjali, Tamra and Mandura bhasma. Most of these drugs possess Madhura rasa, Ushnaveerya and Vata Shamaka properties and may pacify vriddha Vata Dosha. The Balya, Rasayana effects may help in correction of Dhatu kshaya. Pittashamana property probably helps reduction of the Pittaja lakshanas like Daha and Atisweda. Shotahara property may help in reducing the size of enlarged thyroid gland.

**Discussion on Probable mode of action of Kanchanara Guggulu:**

Kanchanara Guggulu is the best known drug in the management of Galaganda and other glandular disorders. The ingredients of Kanchanara Guggulu (Kanchanara, Guggulu, Trikatu Triphala, Trijataka and Varuna) possess Vata- Pitta shamaka property and have Madhura vipaka. Hence they may reduce symptoms like Kshut, Daha, Atisweda, Vepathu, Hridrava, Alpanidrata. Rasayana property of these ingredients will probably help in correcting the dhatu kshaya. Kanchanara and Shunti have Grahi property which may reduce Hyper defecation.

## CONCLUSION

- Overall response was statistically similar in both the Groups with ‘P’ value of 0.422.
- Better clinical therapeutic efficacy was found in patients of Group A, treated with Gandamalakandana Rasa vati internally and a topical application Nichuladi lepa when compared to patients of Group B, treated with only Kanchanara Guggulu vati internally. However, as per statistical analysis both the groups showed no significant results.
- The treatment was moderately effective only in correcting the symptoms clinically whereas no significant changes were seen in the serum T3, T4 and TSH values and change in the size of thyroid gland.

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