

CLINICAL EVALUATION OF SHUDDHA GUGGULU IN HYPOTHYROIDISM PATIENTS

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Abstract:

Hypothyroidism is a condition characterized by abnormally low thyroid hormone production, affects growth, development, and cellular processes. Thyroid gland uses iodine to produce thyroxin (T4)99% and triiodothyronine (T3)1%. Once the hormones are released, a large amount of T4 is converted into T3. Because of autoimmune process reducing the thyroid function, there is a phase of compensation when normal thyroid hormone levels are maintained by rise in TSH, later unbound T4 fall and TSH rise further. Iodine deficiency is prevalent in mountainous regions, central Africa, central South America and northern Asia. WHO estimates about 2 billion people being iodine deficient, an increased prevalence of goiter and cretinism, presenting clinical features like - Tiredness, Weakness, Dry skin, Feeling cold, Hair loss, Poor memory, Concentration, Constipation, Weight gain, Dyspnea, Hoarse voice, Paresthesia, Impaired hearing, Puffy face, Bradycardia, Peripheral edema, Delayed tendon reflex.

The gum resin guggulu contains Guggul sterones Z, E. Guggul sterones I-V Cembrene A and Mukulol, essential oil 64% Myrcene 11% Dimyrcene and Polymyrcene.

In the present study 20 diagnosed Hypothyroidism patients were selected irrespective of their sex in the age group of 20–60 years from the OPD MIAMS, Manipal and administered shuddha guggulu for a period of 60 days. Results are analyzed by the value T3, T4, TSH and main symptoms, before and after the treatment. Statistically highly significant results were observed.

Key words: Hypothyroidism, Guggulu, T3, T4, TSH.

Introduction: Thyroid gland is one of the most important and sensitive endocrine gland, easily responds to stress and stimuli. The major function of the thyroid gland is to control the rate of metabolism. Hypothyroidism¹ is a common disorder now-a-days refers to a condition in which production of the thyroid hormone² below the normal and produces many disorders effects growth, development and cellular metabolism. Any structural or functional defects of thyroid gland that significantly impairs its output of hormones will lead to the hypo metabolic state of hypothyroidism. Hypothyroidism is not just a localized disease, having many symptoms related to many systems of the body. The cause of Hypothyroidism can be classified as 1.Primary – the thyroid failure, 2. Secondary - is due to pituitary TSH deficit and 3.Tertiary – is due to hypothalamic deficiency of TRH. When

hypothyroidism isn't treated, signs and symptoms can gradually become more severe. Constant stimulation of the thyroid gland to release more hormones may lead to an enlarged thyroid (goiter). In addition, individual may become more forgetful, thought processes may slow, or may feel depressed. Advanced hypothyroidism, known as myxedema, is rare, but when it occurs it can be life-threatening. Signs and symptoms include low blood pressure, decreased breathing, decreased body temperature, unresponsiveness and even coma. In extreme cases, myxedema can be fatal.

Hypothyroidism is a disorder effecting Infants, teen and adult and also the condition of other diseases or effect of some treatment. Modern medicine is not succeeded to treat the condition of the hypothyroidism even though the replacement of hormone Thyroxin, reported many adverse effects. Ayurveda is the best option in modern scientific world to invent safe and curative medicines. Shuddha guggulu³ is one of the such efforts considering in the treatment of hypothyroidism patients to bring down symptoms weight gain, fatigue, cold intolerance, hoarseness of voice, constipation, anorexia, gaseous distension, joint pain, muscle cramps, vertigo, hair loss, dry skin, puffiness, menstrual irregularities and to increase production of thyroid hormones to modulate the cellular metabolism.

Materials and methods:

1. Plan of study: A randomized single blind clinical study with pretest and posttest design was adopted, where the patients were given treatment with specific duration with follow up. Specific instructions on diet and life style modification were advised to the patients.

2. Selection of patients: Patients fulfilling the diagnostic and inclusion criteria were carefully selected from the OPD of Muniyal Institute of Ayurvedic Medical Sciences Manipal. In total 24 patients were enrolled for the present study out of which 4 were discontinued the treatment during the course of trail, were dropped out from the study.

3. Diagnostic criteria: Patients having clinical features of Hypothyroidism⁴, and confirmatory diagnostic by Thyroid function test. Detailed physical examination was carried out to assess the condition of the patient.

Inclusion criteria:

- Patients of either sex between 20 to 60 years.
- Fulfilling the diagnostic criteria having signs and symptoms of Hypothyroidism.
- Laboratory report confirms decreased T3, T4 and elevated TSH hormone level
- Patients who have withdrawn thyroid medications before 6 weeks.

Exclusion criteria:

- Patients below 20 years and above 60 years of age.

- Pregnant and lactating mother.
- Diabetes mellitus
- Hypothyroidism more than 10 years.
- Thyroidectomy, Carcinoma of thyroid, Nodular growth.
- Any medication.
- Sever hypothyroidism
- Severe illness
- Cardiomegaly and Bradycardia

Laboratory Investigation: Thyroid function test, Routine hematological, bio-chemical and urine analysis were recorded.

4. Selection of the medicine: Triphala kwatha shodhitha guggulu⁵. Guggulu has to be purified in Triphala kwatha in order to remove toxic substances and render the guggulu easily absorbable. Ayurveda specifies Shodhana (purification) as one of the important procedures before oral administration of guggulu. To purify guggulu in this manner, it was wrapped in a sack of cotton cloth and dipped in simmering Triphala kwatha, which was continuously stirred until all the pure substance of the guggulu was absorbed into the kwatha. When this process was complete, the Triphala kwatha containing the pure guggulu gum resin was solidified and the cotton sack containing the impurities or toxins of the guggulu was discarded. This process was repeated for three times. Solidified guggulu was made pills of 500mg each.

5. Methodology: Triphala kwatha shoditha guggulu 500mg 2 tablet thrice daily with shuddha sukoshna jala in adhibaktha sevana kala for the period of 60 days regularly.

Drop out criteria: Any acute or severe illness, patients not willing to continue the treatment and side affect any.

Concomitant treatment, diet and regimen: Patients on normal diet and avoidance of alcohol, over eating and sedentary life.

Adverse drug reaction and compliance: Clinical criteria were adopted to rule out possible side effect of the study drug. It included the documentation of information related to skin rashes, burning sensation, gastric disturbances, constipation etc.

Follow up: Weekly follow up was advised for proper observation and evaluation of the patients.

Criteria for assessment: The patients were examined weekly changes in symptoms as well as general conditions were assessed. The main Signs and Symptoms weight and height ratio (BMI – Body Mass Index), Joint pain, Muscle cramps and Tiredness were taken for assessment as symptoms

grade parameters. Elevation of value of T3 and T4 to normal range, decline the TSH value to normal range and Blood Cholesterol also taken for the assessment as Laboratory parameters.

Overall assessment of therapy:

1. Complete remission: 100% relief in the chief complaints and obtains the normal value of thyroid function test.
2. Marked improvement: More than 75% relief in the chief complaints and 75% improvement in the value of thyroid function test.
3. Moderate improvement: 50-75% improvement in chief complaints and 50-75% improvement in the thyroid function test.
4. Improved: 25-50% improvement in both chief complaints and thyroid function test.
5. Unchanged: Less than 25% Improvement.

Statistical method followed: Data obtained from the above mentioned study was statistically analyzed by using the paired 't' test.

6. Observations:

Demographic data: Maximum number of patients (60%) were in the age group of 20-30 and 40-50 years, Females (60%), Hindu (95%), House wives (40%), Married (70%), Middle socio-economic status (60%), Dietary pattern vegetarian and mixed both equally distributed (50%), Negative family history (55%), Fresh detection (60%).

Dashavidha pariksha: In the present study maximum number of patients were having Vatapittaja and Sannipathaja prakrithi (each 35%), Pravara sara (65%), Avara samhanana (40%), Pravara satwa (40%), Madhyama Satmya (50%), Madhyama Aharashakthi (65%), Madhyama vyayama shakthi (65%), Pravara pramana (65%), Madhyama vaya (100%).

Srotodusti: Asti vaha sroto dushti were observed in 90% patients, Mamsa vaha in 70%, Medovaha in 65%, Majja vaha in 60%, Sweda vaha in 55%, Pureesha vaha in 50%, Raktha vaha, Rasa vaha and muthra vaha in 30.00%, Arthava vaha in 25% whereas only 10% of patients showed Shukra vaha Sroto Dushti.

7. Result:

In Main symptoms Shuddha Guggulu provided 55.55% relief in Joint pain and 23.68% relief in Tiredness which were statistically highly significant result $p < 0.001$, where as in Body mass index, Muscle cramps and Anorexia provided 2.2%, 45.45% and 38.71% relief respectively which were also statistically highly significant result $p < 0.005$.

In Laboratory parameters Shuddha Guggulu provided 23.73% relief in Triiodothyronine (T3), 26.72% relief in Thyroxin (T4), 45.86% relief in Thyroid Stimulating Hormone (TSH) and 10.47% relief in Blood Cholesterol which were statistically showing highly significant result $P < 0.001$.

Table No.1 Effect of Shuddha Guggulu after 60 days treatment in 20 Hypothyroidism patients

Sl.No.	Main symptoms	Mean score		M.D	% Relief	S.D (±)	S.E (±)	t value	p value
		BT	AT						
1.	BMI	27.68	27.07	0.61	2.2	0.8399	0.1878	3.248	<0.005
2.	Joint pain	1.8	0.8	1.0	55.55	0.7071	0.1581	6.325	<0.001
3.	Muscle cramps	1.1	0.6	0.5	45.45	0.5916	0.1323	3.779	<0.005
4.	Tiredness	1.9	1.45	0.45	23.68	0.4975	0.1112	4.047	<0.001
5.	Anorexia	1.55	0.95	0.6	38.71	0.7348	0.1643	3.652	<0.005

Table No.2 Effect of Shuddha Guggulu after 60 days treatment in 20 Hypothyroidism patients

Sl. No.	Laboratory parameters	Mean score		M.D.	% Relief	S.D (±)	S.E (±)	t value	p value
		BT	AT						
1	Triiodothyronine T3	0.9145	1.199	0.28	23.73	0.2505	0.056	5.08	<0.001
2	Thyroxin T4	5.95	8.12	2.17	26.72	1.4817	0.331	6.55	<0.001
3	Thyroid Stimulating Hormone TSH	57.154	30.94	26.21	45.86	17.685	3.955	6.63	<0.001
4	Blood Cholesterol	229.3	205.3	24	10.47	20.489	4.581	5.24	<0.001

8. Overall effect of the therapy:

Table No. 3 Overall effect of Shuddha Guggulu after 60 days treatment in 20 Hypothyroidism patients

Result	Complete relief		Marked improvement		Moderate improvement		Improved		Unchanged	
	No. of		No. of		No. of		No. of		No. of	
	Pt.	%	Pt.	%	Pt.	%	Pt.	%	Pt.	%
MAIN SYMPTOMS										
BMI	0	00.00	1	07.69	0	00.00	5	38.46	7	53.85
Joint pain	6	33.33	0	00.00	4	22.22	0	00.00	8	44.44
Muscle cramps	4	30.77	0	00.00	5	38.46	0	00.00	4	30.77
Tiredness	1	05.00	0	00.00	8	40.00	0	00.00	11	55.00
Anorexia	5	25.00	3	15.00	1	05.00	0	00.00	11	55.00
LABORATORY PARAMETERS										
T3	3	75.00	1	25.00	0	00.00	0	00.00	0	00.00
T4	4	66.66	1	16.67	1	16.67	0	00.00	0	0
TSH	0	00.00	7	35.00	7	35.00	2	10.00	4	20.00
Cholesterol	4	28.57	1	07.14	2	14.29	6	42.86	1	07.14

Chart-Overall effect of Shuddha Guggulu after 60 days treatment in 20 Hypothyroidism patients

Discussion: The gum resin guggulu contains 32% gum, 19.5% SiO₂, Ca, Mg, Fe, Al, about 1.45% essential oil and faintly aromatic odor. The essential oil of resin has 64% myrcene, 11% dimyrcene and some polymyrcene. The gum resin contains Guggulu sterones Z and E, Guggulu sterones I-V cembrene A and Mukulol. The recent research work done by Dr. Tripathi and others on Animal studies have revealed that guggulu supports healthy thyroid function, by increasing the conversion of less active Thyroxin (T4) to more active Triiodotyronine (T3) through increasing thyroid proteolytic activity and the uptake of iodine into thyroxin, and without increasing the production of Thyroid Stimulating Hormone. The properties of guggulu mentioned in different classical texts are Tridosahara, Shothahara, Vedanasthapana, Vranashodhana, Vranaropana, Jantughna, Rasayana, Agnideepana, Vrushya, Balya, Vatanulomaka, Deepana, Vatahara, Nadibalyakara, Vataroga Medoroga Kleda Kusta Amavata Pidaka Granthi Gandamala nashaka⁶, Twakdosahara, Lekhana etc. Triphala kwatha which is useful in the shodhana of Guggulu have some contributions in the management of the disease. Hareethaki is laxative, increases digestive capacity, reduces excessive fat, Tridosahara increases Agni and Ruchyam and relives Anorexia. Vibheethaki is Tridosahara and Amalaki has rochana, anulomana and rasayana. In this way Shuddha guggulu might have acted collectively based on their pharmacological action in Hypothyroidism patients by increasing the cellular metabolism. Overall data indicate significant improvement with Shuddha guggulu for participants during the trial in both symptoms and laboratory findings used for assessment purposes.

There were no side effects reported during the study trial. Shuddha guggulu appears to be a relatively safe and effective supplement to reduce symptoms of Hypothyroidism patients.

Summary: Shuddha guggulu appears to be beneficial in those who have metabolic syndrome which includes high blood Cholesterol, obesity, and an overall inflammatory pattern. Whether it stimulates thyroid function in every condition is still being evaluated.

Conclusion: The Hypothyroidism can be controlled if the patient follows regular shuddha Guggulu treatment with controlled diet and regimen. From this study we can conclude that the drug Triphala shoditha guggulu as Anti-inflammatory, Analgesic, Muscle relaxant, Rejuvenator, Carminative, Appetizer, Lipolysis, Hypolipidemic, Cellular metabolizer, Energetic and also stimulates Thyroid Hormones. The clinical investigation proved Shuddha guggulu is effective for reduction of pain, stiffness, and improved function, and determined tolerability also in elderly patients. No adverse effect or any unwanted effects are observed during the study. The study further reveals that the Hormone secretions can be modulated by the Ayurvedic drugs. So, the adverse effect and intolerance effect of Hormone replacement therapy can be avoided.

Limitations: The study was conducted on autoimmune subclinical Hypothyroidism patients and the size of the sample was small to draw a generalized conclusion.

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References:

1. Anonymous, Harrison's principle of internal medicine, editor Dan L Longo, volume II, ch. 341, published by Mc Graw-Hill Companies, United States of America, 18th edition, Pg. No. 2918, Pp. 3609.
2. C. C. Chatterjee, Human physiology, editor C. C. Chatterjee, volume I, ch 10, published by A.K. Chatterjee, 11th edition, special reprint 1998, Pg. No. 610, Pp 759.
3. Anonymous, The Ayurvedic Pharmacopoeia of India, Part 1, Volume 1, Published by Government of India Ministry of Health and welfare Dept. edition, 1999. Pg. No. 56, Pp 171.
4. Dr. A.F. Golwalla, Medicine for students, Editors Dr. A.F. Golwalla and Dr. S.A. Golwalla, published by Dr. A.F. Golwalla, 13th Edition, 1985, Pg. No. 426, Pp. 1065.

5. Anonymous, Pharmacopoeial Standards for Ayurvedic Formulations, by Central Council for Research in Ayurveda and Siddha, Revised Edition 1987, Pg. No. 448, Pp. 616.
6. Bhavamisra – Bhavaprakasha, Vidyotini Hindi commentary, by Bhishak Ratna Shri Brahma Shankara Shastry, Prathama bhaga, Bhavaprakasha nigantu, Karpooradivarga, 40,41, published by Choukamba Sanskrit Sansthana, Varanasi, 11th. edition 2004, Pg. No. 204, Pp 959.