

COMPARATIVE EVALUATION OF STRUCTURAL AND FUNCTIONAL CHANGES IN THYROID GLAND AFTER IMPLEMENTATION OF INTEGRATED YOGA MODULE (IYM) AS ADJUNCT THERAPY VERSUS CONVENTIONAL LEVOTHYROXINE THERAPY IN HYPOTHYROID FEMALES

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ABSTRACT

Thyroid disorders have become quite common worldwide over the past few decades. Symptoms of thyroid dysfunction are non-specific and extremely prevalent in the general population. Hypothyroid is the most prevalent thyroid dysfunction and more so in females. Despite the problem being so common, there is no proper treatment modality to control this condition. Many of the as an as have a powerful effect on one or more of the endocrine glands. Practicing some of the specific as an as stimulates the activity thyroid gland and its functions. Hence this study is proposed to generate evidence for yogic practices as an adjunct modality for patients of hypothyroid. The objective of this study is to evaluate the structural and functional changes occurring in patients with hypothyroid as a result of the practice yogic module. The effectiveness of adjunct therapy and the quality of life of patients will also be assessed. 120 female patients of hypothyroid will be randomly allotted to an experimental and control group with 60 patients in each group. Group A will be made to follow the yogic practice module designed along with the conventional treatment whereas Group B will continue with regular conventional treatment. We anticipate that the Yogic module works as an effective adjunct treatment for patients of hypothyroidism and can be used as the first line of treatment in newly diagnosed cases of hypothyroid. Integrated yoga Module will be the new inclusion in the therapeutic model of hypothyroid and also can be studied in different endocrine disorders.

KEYWORDS: Hypothyroid, Yogic Module, adjunct therapy.

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INTRODUCTION

Mankind is in the search of peace and happiness for since long, although Ayurveda and other sciences have taught us various methods to be peaceful, happy, and healthy. Yet it's all in the race to get better and better, humans are inviting various diseases by destroying peace of mind. Ayurveda, ancient Indian science and way of life it talks about the origin of diseases. The texts explain the process of how the emotions suppressed (called Adhis) percolate into the physical body as diseases (Adhijavyahdis). These texts define the philosophical basis for the reversibility of mental body disease (Prasava-pratiprasava model) and provide the principles required for specific posture, breathing, and meditation techniques for various diseases to be established.⁽¹⁾

Yoga considers health and well-being as a fluid continuum and not mere a condition to be reached and sustained.⁽²⁾ The eventual lifestyle stress has blocked the entire energy system and the energy flow imbalance causes different diseases.⁽³⁾ Different thyroid disease studies have shown that 42 million people in India suffer from thyroid disorders.⁽⁴⁾ Specifically, hypothyroidism is the most common thyroid condition in India, affecting one in ten adults.

However, the country does not have an ambitious and scientifically formulated strategy to contain the disease, considering this dismal situation. In India, the prevalence of hypothyroidism is 11%, compared with just 2% in the UK and 4.6% in the USA.⁽⁵⁾ One of the studies indicated that in central India, the prevalence of thyroid disorders is very high and women between the ages of 19 and 45 are more vulnerable to these disorders.⁽⁶⁾ Hypothyroidism, a thyroid disorder is more common in females and refers to an under active thyroid gland, whereby the thyroid gland cannot make enough thyroid hormone to maintain homeostasis in the body.⁽⁷⁾

Hypothyroidism is typically handled to ensure the preservation of natural thyroxin levels in the body by supplementing the body with synthetic thyroxin. Hormone replacement therapy must be used for life on a regular basis.⁽⁸⁾ This disorder decreases the Quality of life of patients. The term, Quality of Life (QoL), is used in healthcare to refer to an individual's emotional, social and physical well-being, including their ability to complete their daily living activities.⁽⁹⁾ As previously stated, hypothyroid disease is a chronic condition frequently requiring lifelong medication. However, a significant

proportion of patients under medication continue to experience a broad range of symptoms, despite thyroid hormone levels returning to normal from medication. Thyroid disease is becoming widespread - one can find personal liberation from the disease with careful attention and knowledge of the deep physiological therapies available through yoga and reverse the disorder in some cases. Therefore, different alternative treatments are evolving day by day to win the fight against illnesses that reduce the quality of life. Asanas are referred to as "sthira sukham asanas," meaning a stable, relaxed body state. The "subtle exercises" that release blockages of physical and mental energy and tone the body-mind for deeper practices are Aasanas.⁽¹⁰⁾

Many asanas have an especially powerful and beneficial effect on one or more of these glands or plexuses; Sarvangasana (Shoulder stand) exerts heavy pressure on the throat region of the thyroid gland associated with the Vishuddha Chakra, for example (Throat Chakra). Practicing this asana stimulates the thyroid gland's proper functioning and its functions.⁽¹¹⁾ In the past, several studies have been carried out to examine the effect of yoga on overall physical and mental health in humans, but the clinical significance of Sharira (Rachana, Kriya, shukshma sharir) from the point of view of chakras, endocrine gland, and autonomic nervous system may thus open up a new arena for ayurvedic medical research.

Rationale of the study

Hypothyroidism being the commonest of thyroid disorders a step has been put forward to study the effect of integrated yoga module as an adjunct therapy in the management of thyroid disorders. Earlier studies did pertaining to this topic are very scare and comprise just pilot studies with a small sample. Also the structural changes have not been previously evaluated. We intend to study the structural and functional changes occurring in the thyroid gland as an effect of yogic therapy. Structurally the focus will be on the changes in size, vascularity, echo texture, calcification, or any mass. Functionally the reduction in levels of TSH along with the dosage of levothyroxine will be evaluated. We shall consider any changes in the structural aspect of the thyroid gland along with a fall in serum TSH levels and reduction in levothyroxine therapy as a significant positive effect.

If this proves successful the study will open an arena for treatment of hypothyroid disorders and possibly other endocrine disorders through yogic practices as an adjunct therapy. Also, this study may be conducted on a larger population to establish the facts. Similar studies can be undertaken on other thyroid disorders. The use of Integrated Yoga as an Adjuvant Therapy on the endocrine gland will help to bring much-needed improvement to the prevalent lifestyle scenario.

OBJECTIVES

Primary objective

1. To assess structural changes occurring in the thyroid gland by the intervention of integrated yogic module as an adjunct therapy.

2. To evaluate changes in the functional aspect of the thyroid gland.

Secondary objectives

1. To compare the effectiveness of Adjunct therapy (Integrated Yogic Module) as compared to conventional levothyroxine treatment.
2. To assess the Quality of life in both groups.

METHODS

Study design

The study will be a Randomized Controlled trial in which diagnosed female patients of hypothyroidism will be equally distributed into two groups. Group A will be the Study group with conventional levothyroxine treatment and the adjuvant treatment of integrated yoga Therapy while Group B will be the control group with only Conventional treatment.

Participants

The study will be instigated at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha. A total of 120 patients will be enrolled and distributed evenly into the two groups by random sampling. The groups will be as follows -

Group A (Study Group): Conventional treatment + Adjunct therapy (IYM)

Group B (Control Group): Conventional treatment.

Inclusion and Exclusion Criteria

1. **Inclusion criteria:** a.) All patients will be adult females between the age group of 20 to 40 years with, already diagnosed cases of hypothyroidism. b.) Having TSH >5mlU/L.c.) Absence of severe psychotic disorders.
2. **Exclusion criteria:** a.) Secondary, tertiary, and congenital hypothyroid will be excluded. b.) Hypothyroid during pregnancy, c.) Patients of Malignancy, Recent Surgery, suffering from Systemic disorders or advised thyroidectomy will be excluded. c.) Already practicing Yoga/exercise for thyroid.

Recruitment

Subjects who are eligible for Integrated Yoga Therapy and fulfill inclusion criteria willing to give written consent will be enrolled for the study. The selected subject will be informed about the study, possible outcome, and side effects of intervention if any. Subjects will be selected on the basis of inclusion and exclusion criteria.

Assessment

Assessment will be done on the basis of the subjective and objective parameters.

Subjective parameters will be:

Symptoms: Fatigue and weakness, Cold intolerance, Dyspnea on exertion, Weight gain, Constipation, Dry skin, Hoarseness, Edema, Decreased hearing, Myalgia and paresthesia, Arthralgia, Menorrhagia

Signs: Diastolic hypertension, Pubertal delay **H/o**, Galactorrhea, Periorbital edema, Puffy facies and loss of

eyebrows, Bradycardia, Slow movement and slow speech, Delayed relaxation of tendon reflexes.

Table 1: Objective parameters

Parameter	Baseline Results	After 30 days	After 60 days	At end of 90 days
Free triiodothyronine (FT3)				
Free Thyroxine (FT4)				
Thyroid stimulating hormone (TSH)				
Body mass index (BMI)				
HDL				
Low-density lipoprotein (LDL)				
USG Thyroid gland	At baseline			At end of study

(Thyroid function test (TFT) comprising of FT3, FT4 and TSH levels will be carried out by Enzyme Linked Immunosorbent Assay –ELISA).

Questionnaire

The questionnaire will be filled by the participants during the follow-up. (based on Quality of life-WHO, Program on mental health world health organization Geneva). The results will be drawn appropriately on the basis of statistical analysis and conclusions will be noted in relation to study objectives.

Details of Intervention Plan

The integrated yogic therapy which will be administered for all the patients includes:

Integrated Yoga Module

(Each session will commence with opening prayer and sithlikarnavyayama- loosening exercises)

Table 2: Sessions

Time	Asana	Pranayama	Bandha	Meditation & Relaxation
Morning (under expert guidance) 40 mins	1. Bhujangasana ⁽¹⁶⁾ 2. Matsyasana 3. Sarvangasana 4. Ustrasana 5. Setu bandha asana 6. Halasana (Each 4 mins)	Anulom- Vilom +Bhramari+ Ujjai Pranayama (5 mins)	Jalandhar bandha (5mins)	Concentration on vishuddha chakra, visualization of colour blue with recitation of beej mantra+ shavasana. (6 mins)
Afternoon (At work place) 10 mins	Grivasanchalan + mild self-neck massage. (5 mins)	-	-	Concentration on vishuddha chakra, visualization of colour blue with recitation of beej mantra. (5 mins)
Evening (10 mins)	-	Anulom- Vilom +Bhramari+ UjjaiPranayama (5 mins)	Jalandhar bandha	Concentration on vishuddha chakra, visualization of colourblue with recitation of beej mantra.

Randomization procedure

With respect to the suitability of the patient for enrollment in the study, the participants will be allotted randomly by computer-generated table method either for the Study group (Integrated Yoga Therapy) or control group.

Methods of data analysis

Sample Size calculated by using percentage (%) Change in a variable in 2 treatment groups for serum TSH concentration. By considering the previous hospital data 15% change in the serum TSH level the sample size is calculated by using the formula for sample calculations, sample size is found 60 patients for each group, Statistical analysis will be carried out by institutional statistician. Statistical assessment will be done through the Un-Paired t-test and Chi-square test.

RESULT

We anticipated that the study group with Adjunct therapy (IYM) had a better outcome as compared to the group with only conventional treatment and if it is shown, it can be the cost-effective alternative treatment modality without any side effect for the patient with Hypothyroidism and which will be again studied in various endocrine disorders as a different treatment modality.

DISCUSSION

Ayurveda and Yogic sciences go hand in hand. Many studies have been done to assess the overall effect of yoga on physical and mental health in humans, but clinical significance from Sharir's (Rachana) point of view of the endocrine gland and autonomic nervous system may thereby open a new arena for ayurvedic medical research. The evidence-based literature on the effects of Yoga on Endocrine disorders is very sparse. Pertaining the hypothyroid disorder, the commonest modality used is conventional levothyroxine therapy. It has been observed that Yogic practices though beneficial, have not been studied in hypothyroid disorders. On extensive literary search, studies on this topic are seldom available, but in that study, the structural part has not been considered. Also, proper mode of action is not explained. Hence, this study is proposed to generate the conventions regarding the Integrated yoga module as an adjunct therapy in hypothyroid disorders.

CONCLUSION

The present modality of integrated yoga therapy as adjunct therapy may serve as an alternate therapy for hypothyroid disorders. If this proves successful further studies may be done on different endocrine disorders.

CONFLICT OF INTEREST

Nil

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ETHICAL CLEARANCE

Taken from institutional ethics committee

REFERENCES

1. Ebnezar J, Nagarathna R, Yogitha B, Nagendra HR, 2012. Effect of integrated yoga therapy on pain, morning stiffness and anxiety in osteoarthritis of the knee joint: A randomized control study. *Int J Yoga*, 5 (1) :28–36.

2. Unnikrishnan A.G. and Menon U.V., 2011. Thyroid disorders in India: An epidemiological perspective. *Indian JEndocrMetab*.15(2), 78-81.
3. Sanjeet Bagcchi, 2014. Hypothyroidism in India: more to be done. *The Lancet: Diabetes and Endocrinology*, vol 2, Issue 10, P778.
4. Bose A., Sharma N., Hemwani N. and Chitnis D.S., 2015. A Hospital based prevalence study on thyroid disorders in malwa region of central India. *International Journal of Current Microbiology and Applied Sciences*, 4(6), 604-611.
5. Poonam Singh, Bhupinder Singh, Rachna Dave, Rakhi Udainiya, 2011. The impact of yoga upon female patients suffering from hypothyroidism, *Complementary Therapies in Clinical Practice* 17 132e134.
6. Raghuwanshi, A, 2011. Studies on Neuro-Endocrinological Correlates of Yogic Pathways. In: P.Nikić, ed. Proceedings “Yoga – the Light of Microuniverse” of the International Interdisciplinary Scientific Conference “Yoga in Science – Future and Perspectives”, Belgrade, Serbia. Belgrade: Yoga Federation of Serbia, p. 10-18.
7. M V Rao, 2011. *The Essence of Yoga*, first ed, chaukhambhaorientalia, Varanasi, pg 186.
8. *Integr Med*. aop,
9. Sridip Chatterjee & Samiran Mondal, 2017. Effect of combined yoga programme on blood levels of thyroid hormones: A quasi-experimental study. *Indian journal of Traditional Knowledge*; Vol. 16 (suppl), , pp S9-S16.
10. Agharanaya JC, 1990. Clinical usefulness of ELISA technique in the assessment of thyroid function. *West Afr J Med*; 9(4): 258-63.
11. Prasanna Kumar S, Arakhita S, Gangadhar S, Smaraki M, Kulani B, 2020. Newborn Screening for Congenital Hypothyroidism in Institutional Set Up in an Urban Area in Odisha. *Int J Cur Res Rev*. Vol 12 Issue 24, 179-182.

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