# A Prospective Cross-Sectional Study on Drug Adherence, Prescription Patterns, Associated Comorbidities and Quality of Life in Patients with Sub-clinical Thyroid Disorders

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#### **ABSTRACT**

Aim: The evident rise in prevalence of Thyroid disorders in India emphasizes on patient care to be addressed with few challenges like failure to monitor disease condition, poor medication adherence and low frequency of follow-up visits with the physician. Objectives: Objective of this study is to assess the thyroid function and quality of life in patients with subclinical thyroid disorders. Materials and Methods: A cross-sectional study was conducted which comprised of 142 patients with subclinical thyroid disorders and were assessed for their prescription patterns, medication adherence, quality of life and other risk factors using case report form and other standardized scales like Thypro scale and Morisky medication adherence scale. Results: Patients with comorbidities like hypertension, diabetes mellitus, renal disorders and cardiovascular were found to be high and few patients even complained of sleep disorders, hair loss/alopecia and arthritis. Among these, incidence of renal diseases was found to be high in patients with subclinical thyroid disorders. Prescription pattern showed majority of patients with subclinical hypothyroid were prescribed levothyroxine 25mcg and carbimazole10mg for patients with subclinical hyperthyroid. Conclusion: Patients having high medication adherence showed good quality of life and those with poor adherence to medications showed poor quality of life which shows significant relationship between the medication adherence and quality of life.

**Keywords:** Subclinical thyroid disorders, Medication adherence, Quality of life, Prescription patterns, Comorbidities.

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## INTRODUCTION

Thyroid hormones are a collection of hormones secreted by the thyroid gland, a ductless alveolar, butterfly shaped gland. The predominant hormone is thyroxine, known as T4. Thyroid hormones have a wide range of effects on metabolism, growth and development, and body temperature. Thyroid hormone levels must be adequate for brain growth during childhood and adolescence. Subclinical Thyroid dysfunction is accompanied with a change in serum thyroid-stimulating hormone levels (reference range: 0.45 to 4.50 U per mL) and normal levels of free thyroxine and triiodothyronine. The complications for subclinical thyroid dysfunction include cardiovascular risks, functional capacity and cognitive impairment.



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Subclinical hypothyroidism (SCH) is characterized by the existence of elevated Thyroid Stimulating Hormone (TSH) levels in the presence of normal free thyroxine (free T4) levels. SCH prevalence increases with age in women and is more common in elderly females (7-18%) than males (2-15%). Most common causes of hypothyroidism are iodine deficiency, Hashimoto's thyroiditis. Other causes include subtotal thyroidectomy, radioactive iodine therapy and medication induced hypothyroidism. It is asymptomatic usually but can present with Integumentary, gastrointestinal, cardiovascular, reproductive and neurological symptoms as of hypothyroidism. Levothyroxine is the choice of therapy, with starting dose of 1.6 mcg/kg in the absence of cardiovascular disease and 25 mcg in patients with cardiovascular disease. 1,2

This study aims to promote awareness on medication adherence, disease monitoring and emphasis on lifestyle modifications in Subclinical thyroid disorders and to assess the correlation between thyroid function and quality of life in patients with subclinical thyroid disorders.

#### MATERIALS AND METHODS

#### **Source of Data**

- Case report form,
- Prescriptions of patients,
- Patient case sheet/medication chart,
- Lab reports,
- Patient questionnaire (Thypro scale, Morisky scale).

# Sampling method

The sample size was determined to be 142 participants. The level of significance was set at 0.05, with a margin of error of 5% and a confidence interval of 95%.

# Study design

This is a prospective observational cross-sectional study.

#### Inclusion criteria

- Patients aged between 18 to 75 years old.
- Patients with Diagnosis of either sub clinical Hyperthyroidism or Hypothyroidism.
- Patients with available Laboratory blood test results of thyroid functions (TSH, T3 and T4) levels not more than 6 weeks before participation.

## **Exclusion criteria**

- Pregnant and lactating women.
- Patients with thyroid malignant tumor or with cancer.
- Patients who underwent major surgery recently.
- Central hypothyroidism.
- Post-surgical or post radio therapy hypothyroidism.
- Patients taking drugs with alter the thyroid functional tests.
- Morbid obesity.

## **Study tools**

Self-designed case report form: A data collection form will be designed to collect subject's demographic and disease specific aspects.

THYPRO-Thyroid-specific Health Related Quality of Life Questionnaire: is a specific tool designed to assess the impact of Thyroid disorders in patient's quality of life. It consists of 85 questions summarized in 13 scales measuring aspects of QoL relevant to thyroid patients.

Morisky Medication Adherence Questionnaire (MMAS): is one of the most widely used mechanisms to assess patient adherence to medications.

## **Statistical Analysis**

Data collected from case report form, questionnaires was used for data entry. The relevant data gathered was input into an Excel spreadsheet, and appropriate statistical analysis was conducted. Descriptive statistics was done by using SPSS software to determine mean and standard deviation of collected data. The statistical tool independent *t*-test was performed to determine *p*-value between the different collected data. The *p*-value was set at <0.05 and confidence interval was 95%.

## **Ethics and consent**

Institutional Ethical Committee of Kamineni Academy of Medical Sciences, Research Centre and Hospital approved the survey; Chairperson of Institutional Ethics Committee gave permission to conduct the study. The study participants received an overview of the research, and their willingness to participate was confirmed.

## **RESULTS**

A Total of 142 patients of Subclinical Thyroid Disorders were screened according to Inclusion Criteria. Table 1 indicates gender wise distribution of patients. Percentage of females known with subclinical thyroid disorders was more in number (77%) than male (23%).

Out of 142 patients, 124 patients had comorbities where incidence of renal disorders, diabetes, hypertension and cardiovascular diseases is seen to be high among patients with sub-clinical thyroid disorders shown in Figure 1.

Table 2 indicates the frequency of monitoring in patients with sub clinical thyroid disorders among which maximum number of patients monitored their disease once in a year.

Among 142 subjects a maximum number of 121 patients were said to be low adherent to medications, 15 patients show medium adherence and 6 patients show high medication adherence shown in Figure 2.

The number of patients with subclinical hypothyroid disorders is found to be higher than sub clinical hyperthyroid disorders. Out of 102 sub clinical hypothyroid patients, 52 patients were prescribed with tablet THYROXINE of dose 25 mcg, 24 patients with a dose of 50 mcg, 8 patients with dose of 37.5 mcg and each 4 patients with a dose of 125 mcg, 100 mcg, 75 mcg and 12.5 mcg respectively. All patients diagnosed with sub clinical hyper thyroid disorder were prescribed with CARBIMAZOLE of 10 mg shown in Figure 3.

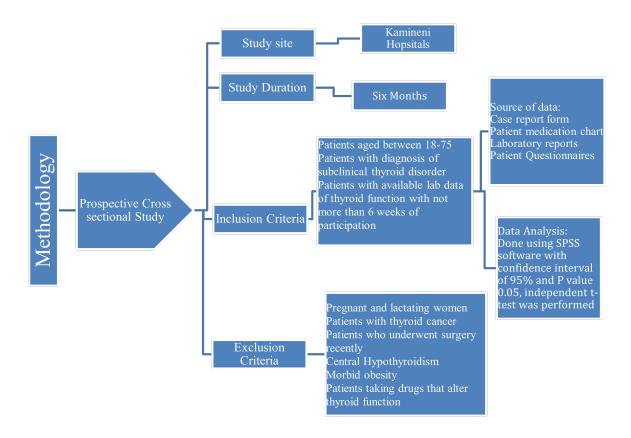


Table 1: Gender wise distribution.

SI. No.	Gender	Number of Patients	Percentage
1	Male	33	23%
2	Female	109	77%
3	Total	142	100%

Among all the thyroid symptoms - Shortness of breath, heat sensitivity and increased sweating are the most commonly shown symptoms. Table 3 indicates thyroid symptoms shown by 142 patients.

Majority of the patients experienced cognitive symptoms with increased confusion and difficulty in concentration being the most common shown in Figure 4.

Out of 142 patients, 112 patients were experienced with emotional susceptibility, 109 patients with anxiety and 104 patients with depression. Table 4 indicates mental health status of patients with subclinical thyroid disorders.

Subclinical thyroid disorder effects social life of 104 patients, daily life of 88 patients, sexual life of 40 patients and 80 patients had cosmetic complaints too shown in Figure 5.

Patients with higher TSH levels showed poor quality of life and those with TSH levels within normal range have good quality of life shown in Figure 6.

An independent sample t-test was performed and p-value was found to be <0.05 which is considered as statistically significant.

# **DISCUSSION**

Low medication adherence leads to complications like cardiovascular diseases, osteoporosis, eye disorders, and mental health conditions and can even affect reproductive health. This article explores the interplay between thyroid dysfunction and these health outcomes. We review recent studies that shed light on the importance of timely recognition and effective treatment of thyroid dysfunction, emphasizing its impact on heart failure, fracture risk, anxiety, and depression. In this study around 28 patients were hypertensive whereas 20 patients have cardiovascular issues, while hypertension is not

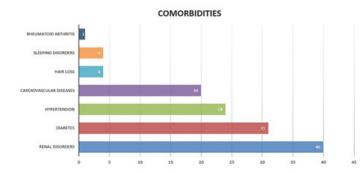


Figure 1: Comorbities.

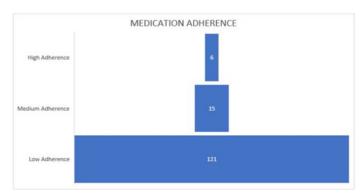


Figure 2: Medication adherence.

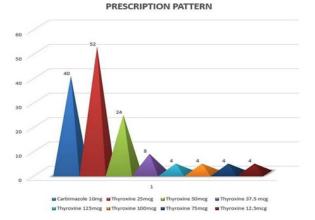


Figure 3: Prescription pattern.

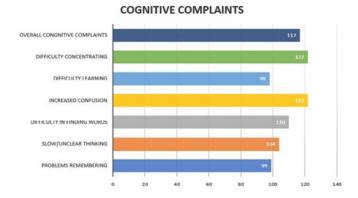


Figure 4: Cognitive complaints.

Table 2: Frequency of monitoring.

Frequency of monitoring	Frequency	Percentage
Once in a year	102	57.74%
More than once in a year	25	17.6%
Once or twice every six months	15	7.04%

Table 3: Thyroid Symptoms.

Symptoms	Frequency	Percentage
Goiter	37	26%
Heat sensitivity	60	42%
Increased sweating	60	42%
Palpitations	40	28%
Sensitive to cold	51	36%
Shortness of breath	96	68%
Swollen hands/feet	23	16%
Trembling hands	44	31%

Table 4: Mental Health status.

Symptom	Frequency	Percentage
Anxiety	109	77%
Depression	104	73%
Emotional Susceptibility	112	79%

classified as a cardiovascular disease; it significantly contributes to the development of disease. Thyroid dysfunction can impact both systolic and diastolic blood pressure; heart mass, ejection fraction, and overall cardiac output. These effects may play a role in the development and progression of heart failure. Similarly, Bernadette Biondi conducted a study on "Heart failure and thyroid dysfunction and the outcome of this analysis suggests that patients with untreated overt thyroid dysfunction are at increased risk of HF and concluded that timely recognition and effective treatment of cardiac symptoms in patients with thyroid dysfunction is mandatory because the prognosis of HF may be improved with the appropriate treatment of thyroid dysfunction. Hongling Zhu et al. concluded that Subclinical hyperthyroidism could induce additional risk of fractures at any, hip, spine, and non-spine, whereas subclinical hypothyroidism did not have any impact on fractures. Moreover, BMD at the lower distal and ultra-distal forearms might be affected by subclinical hyperthyroidism, and higher femur neck BMD could be affected by subclinical hypothyroidism. In this study, patients experienced mental health challenges, including anxiety, depression, and heightened emotional sensitivity. Similarly, Mustafa Sait Gönen et al. found that subclinical thyroid dysfunction increases the anxiety of patients whether hyperthyroid or hypothyroid. Mood

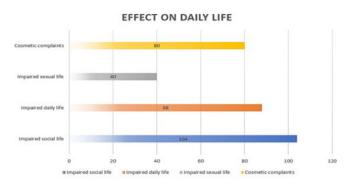


Figure 5: Effect on daily life.

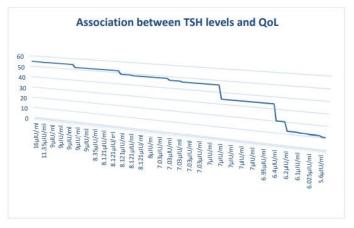


Figure 6: Association between TSH and Quality of Life.

changes especially anxiety due to subclinical thyroid dysfunction may have an important impact on the patient's quality of life. Rong Tang et al. conducted a meta-analysis revealing a positive association between Subclinical Hypothyroidism (SCH) and the risk of depression, particularly in individuals aged 50 years and above. This underscores the importance of vigilance toward depressive symptoms in those with SCH. Raphael Hirtz et al. examined the relationship between parameters of thyroid function and Beck Depression Inventory-II (BDI-II) scores and concluded that the prevalence of subclinical hypothyroidism and of thyroid autoimmunity in depressed adolescents is increased. The etiology of these observations is not well understood, and underlying relationship between thyroid function parameters and depression warrants further investigation. Moreover, thyroid autoimmunity may constitute an additional risk factor for depression on its own.3-7 Thyroid disorders have a significant impact on patients' overall quality of life, affecting physical, mental, and social well-being. In the present study Subclinical thyroid disorders had a negative effect on the quality of life of 122 patients among 142 subjects. These negative effects are reflected as impaired social life (104 patients), impaired daily life (88 patients), impaired sexual life (40 patients) an also cosmetic complaint (80 patients).

In this study, results showed statistical difference in tiredness, emotional susceptibility, impaired daily life and cosmetic complaints. Additionally, difference was seen in goiter, hyperthyroid, hypothyroid and eye symptoms in both groups. The two groups with TSH<6 and TSH>6 showed differences in overall health related quality of life with mean value 20.65 and 82.18 respectively. Patients with a TSH level below 6 encountered fewer symptomatic issues, highlighting the significance of medication adherence and its impact on overall quality of life.

## **CONCLUSION**

Prescription patterns showed that the majority of the subclinical hypothyroid patients were prescribed with levothyroxine and the most prescribed dose was 25 mcg and patients with subclinical hyperthyroidism were prescribed with carbimazole 10 mg. Patients with comorbidities like hypertension, diabetes mellitus, renal disorders and cardiovascular were found to be high and few patients even complained of sleep disorders, hair loss/alopecia and arthritis. Out of all these, incidence of renal diseases was found to be high in patients with subclinical thyroid disorders. Medication adherence was found to be poor and frequency of monitoring is low in the majority of the patients which shows the need for proper patient education. Cognitive complaints were seen in 82% of the patients which comprises symptoms like problems in remembering, slow or unclear thinking, difficulty in finding words, increased confusion, difficulty in learning and concentrating which puts them at risk of dementia and other related diseases. Overall, 76% of the patients had mental health issues like anxiety, depression and emotional susceptibility. Patients having high medication adherence showed good quality of life and those with poor adherence to medications showed poor quality of life which shows a significant relationship between the medication adherence and quality of life.

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# **CONFLICT OF INTEREST**

The authors declare that there is no conflict of interest.

#### **ABBREVIATIONS**

**BMD:** Bone Mineral Densit; **HF:** Heart Failure; **QoL:** Quality of Life; **SCH:** Subclinical Hypothyroidism; **SPSS software:** Statistical Package for the Social Sciences; **TSH:** Thyroid Stimulating Hormone; **T4:** Thyroxine; **T3:** Triiodothyronine.

## **SUMMARY**

In this study we assessed prescription patterns, medication adherence associated comorbidities and effect on quality of life in patients with subclinical thyroid disorders. Patients were observed to have conditions such as hypertension, diabetes, cardiovascular disease, renal disease, mental health issues and cognitive challenges. Patients having high medication adherence showed good quality of life and those with poor adherence to medications showed poor quality of life. Our findings highlight the importance of addressing medication adherence, cognitive

symptoms, and mental health in patients with subclinical thyroid disorders.

# **REFERENCES**

- Adlin V. Subclinical hypothyroidism: deciding when to treat. Am Fam Physician. 1998; 57(4): 776-80. PMID 9491000.
- Gosi SKY, Garla v V. Subclinical hypothyroidism. StatPearls. Published online 2021 [cited 2022]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK536970/.
- 3. Biondi B. MECHANISMS IN ENDOCRINOLOGY: heart failure and thyroid dysfunction. Eur J Endocrinol. 2012; 167(5): 609-18. doi: 10.1530/EJE-12-0627, PMID 22956554.
- Zhu H, Zhang J, Wang J, Zhao X, Gu M. Association of subclinical thyroid dysfunction with bone mineral density and fracture: a meta-analysis of prospective cohort studies. Endocrine. 2020; 67(3): 685-98. doi: 10.1007/s12020-019-02110-9, PMID 31721088.
- SAIT GÖNEN M, KISAKOL G, SAVAS CILLI A, DIKBAS O, GUNGOR K, INAL A, et al. Assessment of anxiety in subclinical thyroid disorders. Endocr J. 2004; 51(3): 311-5. doi: 10.1507/endocrj.51.311, PMID 15256776.
- Tang R, Wang J, Yang L, Ding X, Zhong Y, Pan J, et al. Subclinical hypothyroidism and depression: A systematic review and meta-analysis. Front Endocrinol. 2019; 10: 340. doi: 10.3389/fendo.2019.00340, PMID 31214119.
- Hirtz R, Libuda L, Hinney A, Föcker M, Bühlmeier J, Antel J, et al. Lack of evidence for a relationship between the hypothalamus-pituitary-adrenal and the hypothalamus-pituitary-thyroid axis in adolescent depression. Front Endocrinol. 2021; 12: 662243. doi: 10.3389/fendo.2021.662243, PMID 34108936.

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