A Study to Evaluate Prescription Pattern, Adherence to Medication and Quality of Life in Indian Patients Suffering from Thyroid Disorders

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Abstract

Introduction: Deficiency of thyroid hormones or "Hypothyroidism" is usually managed by oral thyroid hormone replacement drugs. Whereas drugs which block synthesis or conversion of thyroid hormones are employed in "Hyperthyroidism". Since thyroid hormones play role in many bodily functions, its disturbances affect Quality of life (QoL). Also, due to the chronic nature of thyroid disorders, treatment adherence is quiet challenging.

Objectives: To evaluate prescription pattern, QoL and patient's adherence to treatment for thyroid disorders in Indian population.

Methodology: Case record form containing patient's demographic, clinical profile, diagnosis, prescription drugs (with dose, duration and frequency) was noted. The QoL of each patient was assessed by a 30 item questionnaire specific for thyroid disorder. Drug adherence was tested by (4 item) Morisky Green Levine Test questionnaire. The collected case record forms and questionnaires were analyzed. P value ≤ 0.05 was considered as statistically significant.

Result: Out of 126 patients, nearly three-fourth of patients were diagnosed to be suffering from hypothyroidism (Group1; n = 94) and one-fourth (Group 2; n = 32) from hyperthyroidism. Patient demographics with respect to mean age and gender distribution (40.03 ± 14.07 years; M:F = 0.08 and 39.34 ± 11.71 years; M:F = 0.14 respectively for Group 1 and 2) was comparable. Levothyroxine for hypothyroidism followed by carbimazole for hyperthyroidism were the most prescribed drugs in our study population. Nearly 70% of thyroid patients were highly adherent to medication in both the groups (Group 1 - 69.14%; Group 2 68.75%), possibly due to oral single daily dose regime. QoL was 65% in our study population (Group 1: 64% and Group 2: 67%). The mean QoL scores and mean adherence scores were not statistically different between both the groups. We found a significant positive correlation between occupation with spiritual score, gender with psychological score and adherence with spiritual score. We also observed a significant negative correlation between age and physical score and gender and spiritual score.

Conclusion: We found 65% level of adherence and 70% QoL in our study population. Hyperthyroid patients had higher QoL but lower level of medication adherence as compared to hypothyroid. Focused educational programmes, better doctor-patient and pharmacist-patient relationships with good prescribing practices can further foster this.

Keywords: Adherence; Carbimazole; Hypothyroidism; Hyperthyroidism; Levothyroxine; Prescription Patterns; Quality of Life

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Introduction

Thyroid disorders are among most common disorders in both developed and developing countries. Being under explored in developing countries like India. In India about 42 million people suffer from a thyroid disorder more commonly hypothyroidism affecting 11.4% of women and 6.2% men [1]. Prevalence of hyperthyroidism in India in community survey is 1.6% [1].

Hypothyroidism is managed by oral thyroid hormone replacement drugs viz. Levothyroxine and Liotrix [2]. Hyperthyroidism is managed by drugs blocking synthesis of thyroid hormones (Propylthiouracil and Methimazole). Beta blockers, radioactive Iodine and surgery are less frequently employed [2]. Drug prescription studies determines its adverse effects and relations between other co-morbid illness and drug utilization pattern. Levothyroxine is the treatment of choice in hypothyroidism. Pre-existing hypothyroidism patients generally require increased Levothyroxine doses during pregnancy. Hyperthyroidism in pregnancy is usually associated with Graves’ disease. They are treated with propylthiouracil the 1st and methimazole in 2nd and 3rd trimesters [3].

Non-adherence to medications is a major cause of treatment failures [4]. It is estimated that only 50% of patients follow treatment. Noncompliance due to side effects and long duration of therapy contributes to substantial worsening of disease [5,6]. A joint consideration of Laboratory parameter TSH and patient’s relief together with a more personalized approach is required to address recent surge in patient complaints [7]. Quality of life (QOL) in patients with thyroid disorders has been documented marginally low [8]. Persistent complaints, like reduced QOL, daily functioning, and residual hypothyroid related symptoms, are common in hypothyroid patients despite replacement therapy. The extent of disease burden in the population and need for life-long therapies makes it a disease affecting QOL. Measuring QOL using standardized questionnaires can predict clinical evolution and functional change that will lead to develop better treatment options improving patient’s lifestyle. Need for medication adherence in thyroid disorders is imperative. Hence the study will address both QOL and adherence to prescribed drugs.

Aims and Objectives

To evaluate prescription pattern, QOL assessment and patient’s adherence to treatment for thyroid disorders (hyperthyroid and hypothyroid) among Indian population in a tertiary care teaching hospital.

Methodology

Study design

This was a prospective cross-sectional study of 8 weeks duration and was carried out on the outpatients visiting Endocrinology OPD at a tertiary care teaching hospital. The study was started after obtaining permission from the Institutional Ethics Committee. Voluntary written and informed consent of the patient was obtained in their vernacular language. Confidentiality of the data was maintained. Male and female patients were enrolled irrespective of their ethnicity. However, following selection criteria were applied. Patients of either gender who were > 18 years of age and who gave their written informed consent. All patients were diagnosed with thyroid disorder (hyperthyroid or hypothyroid) and receiving treatment were included. Patients who suffered from any severe co-morbid conditions that can affect adherence and QoL or who couldn’t understand the questions asked by investigator or who were not in charge of their own medications (Example- under supervision of a caregiver) were excluded. The case record form contained patient’s demographic and clinical profile, his/her provisional diagnosis. Drug related details such as generic and brand names, dose form, duration, frequency of therapy and other co prescribed drugs was also noted.

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Questionnaires

QoL of each patient was assessed by a 30-item questionnaire named as QoL-Thyroid Version that is specific for thyroid disorder [10]. This is a disease specific QOL instrument which is administered in patients diagnosed/treated from thyroid cancer. It contains four domains—physical wellbeing, psychological wellbeing, social concerns and spiritual wellbeing. Several questions have multiple sub-sections; some of the questions were specific for thyroid cancer, so they were not applicable in our study. Hence, 30-item constitutes 48 questions. Generally, for each question, scores range from scale of 0 i.e. worst outcome to 10 i.e. best outcome. However, several questions contain reverse anchors and therefore when coded, these items were reversed. For example, when a subject circled “3” on such a question, recorded score was 7 (10 - 3 = 7). The questions contained in items 1, 3, 10 - 23, 27 were reversed. Subscales were created for analysis purposes by adding all the items within a domain and creating a mean score. Grand QoL score (out of a total score of 480) was also calculated for each patient, where lower score represented worst QoL.

Drug adherence was analyzed for each patient using the basis of Morisky Green Levine Test questionnaire [9]. This questionnaire is standardized, pre-validated and well tested. It consists of four questions, where answer to each as "NO" suggests adherence. Scoring was done by coding “YES” answer as “0” and “NO” as score “1”. Based on the additive score of these 4 questions, total adherence score was computed. Score 4 signifies high adherence, score 3 and 2 signifies medium adherence while score 1 and 0 signifies low adherence.

Statistical analysis

Data was analyzed using statistical software (SPSS version 26) and Microsoft excel 2016. Quantitative variables were expressed in mean ± standard deviation, whereas categorical variables were expressed in numbers and percentages (%). Descriptive statistics was used for the assessment of baseline characteristics. Shapiro-Wilk test was used to analyze the compliances of datasets with normal distribution. Unpaired Student “t” test was used to compare mean differences between the groups. Pearson correlation coefficient was used for finding correlation between different variables. P values ≤ 0.05 was considered as statistically significant.

Observations and Results

The study population consisted of 126 patients.

Demographic and clinical characteristics

1. Diagnosis: Out of 126 patients, three-fourths of patients had hypothyroidism viz. 94 (74.60%) patients and 32 (25.39%) patients had hyperthyroidism. Hypothyroid and hyperthyroid patients were grouped into Group1 and Group 2, respectively.

2. Age and gender distribution: The mean age of the patients in Group1 and 2 was found to 39.34 ± 13.49 and 40.03 ± 13.49 years, respectively.

3. Co-morbid illness: In Group 1, 7 patients had different co-morbid illness, among which Hypertension was most common (6.38%), followed by Type II Diabetes Mellitus (15.62%). Least common were Psychiatric illness, cardiac abnormalities, Anemia and Concentration Problem (1.06%). In Group 2, Hypertension and Type 2 Diabetes Mellitus were most common (18.75% each).

4. Chief complaints: In Group 1, fatigue was the most common presenting complaint (19.14%). While weight loss (25%) was most common in Group 2.

5. Level of education: Majority of patients in both groups received only primary education till class 7.

6. Occupation: Majority of patients in both groups were employed in unskilled labour like “housewife”.

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**Figure 1:** Age distribution of study population.

**Figure 2B and 2B:** Gender distribution in group 1 and group 2.
Drug prescription pattern in thyroid patients

A total of 270 drugs were prescribed to 126 patients, making an average of 2.14 per patient. All the patients in Group 1 received oral thyroid hormone replacement in form of “Levothyroxine” tablet. Thirty out of thirty-two patients in Group 2 were prescribed oral “Carbimazole” tablet and remaining 2 received “propylthiouracil” tablet as anti-thyroid drugs. Fourteen of them additionally received “propranolol” tablet. Patients were also treated for their co-morbid illnesses with suitable drugs via oral and/or subcutaneous routes as appropriate.

Quality of life assessment

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Domain: Physical well being

Fatigue, followed in decreasing order by aches and pain, swelling, weight gain were the most affected items in Group 1 patients. Whereas, fatigue, followed in decreasing order by aches and pain, skin and hair changes and tolerance to heat were the most affected items in Group 2 patients. Motorskills/Coordination was least affected in both the groups. The best score for this domain was 130 and average score in our study population was 74.59 ± 16.6 (74 ± 16.6 and 77.03 ± 16.5 in Groups 1 and Group 2 respectively). Hyperthyroid patients showed higher mean score in this domain as compared with hypothyroid, although difference was not significant (p = 0.37).

Domain: Psychological well being

Most of the patients in both groups reported feelings of anxiety, followed by experienced distress upon their initial diagnosis. Withdrawal from thyroid hormone, change in appearance and ability to remember things were additional concerns in Group 1 patients. Change in self-concept and satisfaction in life were least affected items for both the groups. Additionally, "Useful one feel" and "control of things" in life were less affected in Group 2. The best score for this domain was 140 and average score in our study population was 97.84 ± 17.5 (97.08 ± 17 and 99.56 ± 16.7 in Groups 1 and Group 2 respectively). Hyperthyroid patients showed higher mean score in this domain as compared with hypothyroid, although difference was not significant (p = 0.49).

Domain: Social concerns

Very low score was seen in question related to support they get. Least affected domains were interference with activities at home, impact on sexuality and interference in personal relationships. The best score for this domain was 140 and average score in our study population was 95.63 ± 19.1 (93.74 ± 20.41 and 100.7 ± 14.3 in Groups 1 and Group 2 respectively). Hyperthyroid patients showed higher mean score in this domain as compared with hypothyroid, although difference was not significant (p = 0.07).

Domain: Spiritual well being

Very low score was seen in question regarding meditation. Least affected domains were their reason for being alive, how hopeful they feel and their participation in religious activities. Group 1 patients were more uncertain about their future in comparison with Group 2. The best score for this domain was 70 and average score in our study population was 44.20 ± 6.5 (43.58 ± 6.7 and 46.18 ± 5.9 in Groups 1 and Group 2 respectively). Hyperthyroid patients showed higher mean score in this domain as compared with hypothyroid, although difference was not quite significant (p = 0.05).

Grand QoL score

The composite and domain wise percentage of mean score was computed for each patient and is presented in figure 5. The average GrandQoL score in our study population was 312.27 ± 46.8 (Group 1 and Group 2 - 308.40 ± 49.2 and 323.5 ± 38.4 respectively; difference between the groups was not significant; p = 0.11). It is evident that these mean scores are below best score of 480 in both the groups; suggesting that average QoL is around 65% in our study population (Group 1: 64% and Group 2: 67%). It can also be inferred that “physical wellbeing” domain (57%; Group 1: 57% and Group 2: 59%) was most affected and “psychological well being” domain was least affected (70%; Group 1: 69% and Group 2: 71%). The reliability of QoL questionnaire used in our study was confirmed by a relatively high internal consistency (Cronbach’s Alpha of 0.8).

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Adherence to medication

Out of 126 patients, 66 (70.21%) in Group 1 and 23 (71.87%) in Group 2 responded “NO” to the question-1 “Do you ever forget to take your medicine?” (Refer figure 6). When asked in question-2 “Are you careless at times about taking your medicine?”, 4 (12.5%) and 28 (87.5%) patients, in groups 1 and 2 respectively, answered “NO”. Only 1 patient in each group (Group 1: 1.07% and Group 2: 3.12%) agreed to the question-3 “When you feel better, do you sometimes stop taking your medicine?”. Only 1 patient (1.07%) in Group 1 and none in Group 2, stopped taking medicine when she felt worse (question-4) (Refer figure 6). High adherence (i.e. score “4”) was seen in 69.14% of patients in Group 1 and 68.75% of patients in Group 2. Medium adherence (i.e. score “3” and “2”) was seen in 29.78% of patients in Group 1 and 28.12% of patients in Group 2. The mean adherence scores (Group 1: 3.57 ± 0.72 vs Group 2: 3.56 ± 0.75; p = 0.96) were not statistically different between both the groups.
Correlation of variables with QOL

In our study population, there was a significant positive correlation between occupation with spiritual score ($r = 0.2; p = 0.003$), gender with psychological score ($r = 0.1; p = 0.03$) and adherence with spiritual score ($r = 0.2; p = 0.004$). We also observed a significant negative correlation between age and physical score ($r = -0.18; p = 0.04$) and gender and spiritual score ($r = -0.2; p = 0.002$).

In group 1, age had significant negative correlation with Physical domain ($r = -0.2; p = 0.047$) and GrandQoL scores ($r = -0.2; p = 0.05$). In this group, occupation of patient had very significant positive correlation ($r = 0.3; p < 0.001$) but, gender had significant negative correlation with spiritual domain score ($r = -0.2; p = 0.004$). We also observed a significant positive correlation with spiritual domain and adherence score ($r = 0.2; p = 0.009$). In group 2, we found a significant positive correlation of gender with psychological ($r = 0.5; p = 0.003$), social ($r = 0.4; p = 0.025$) and GrandQoL scores ($r = 0.3; p = 0.03$).

Figure 7: Correlation of age with physical wellbeing domain of QoL.

Discussion

The prevalence of hyperthyroidism ranges from 0.2% to 1.3% and hypothyroidism from 1% to 2%, rising to 7% in individuals aged between 85 and 89 years in iodine-sufficient parts of the world [11]. In our study hypothyroidism dominated the population by 49.21% which is more common. Incidence of thyroid dysfunction was 74.60% for hypothyroidism and 25.39% for hyperthyroidism. Females were far more affected than males (M:F = 0.1).

Age range mainly involved was 31 - 40 years in both thyroid disorders which was similar to a study by Shakya Shrestha S [12]. This disease engulfed younger population too but on the contrary it was well controlled by thyroid supplements or anti-thyroid drugs. About 37.50% hyperthyroid patients and 27.65% hypothyroid patients were productive to the society and employed in some capacity. Prevalence of hypertension in hyperthyroid patients was due to excess T3 leading to metabolic and hemodynamic changes: metabolic rate, cardiac preload and ventricular contractility increases while systemic vascular resistance decreases, causing increased cardiac output and hypertension and in hypothyroid patients may be due to decreased ventricular filling and cardiac contractility together lead to low cardiac output. Increase in systemic ventricular resistance, slowed ventricular relaxation, decreased metabolic rates, decline in peripheral oxygen demands leads to heart failure [13]. Thyroid hormones directly control insulin secretion thus associated with Type II Diabetes Mellitus. In
hypothyroidism, there is a reduction in glucose-induced insulin secretion by beta cells, and the response of beta cells to glucose or catecholamine is increased in hyperthyroidism due to increased beta cell mass. Moreover, insulin clearance is increased in thyrotoxicosis [14].

Therapy of disease depends on pharmacotherapeutic management using wide array of Anti-thyroid drugs and thyroid supplements. Hence this study evaluated drugs prescribed in such patients suffering from thyroid disorders. Hypothyroidism needs replacement therapy of oral Levothyroxine (12.5 - 200 mcg) given to all patients as prescribed in study [12]. T4 being inexpensive can be given as single daily dose. It had predictable action, easy administration and laboratory evaluation. Triiodothyronine T3 was not used in any patient in study due to its rapid action (half-life one day). This could cause alternation of cardiac function. T3 is advocated to be given in Myxedema crisis. In Hyperthyroidism Carbimazole was commonly prescribed. Dose ranged from 5 mg - 20 mg. It is one of the most potent long acting Anti-thyroid agent acting at various steps of thyroid synthesis, thus given once a day [15]. Propranolol blocks peripheral conversion of T4 to T3 was administered in 43.75% of hyperthyroid patients. Very few patients received radioactive iodine.

Low scores were seen for Physical well being such as fatigue, aches and pain, specially in hypothyroid patients, in whom these were the most common chief complaints due to low BMR. Motor skills were least affected. While evaluating psychological well being; low scores were seen in questions to anxiety and how distressful their initial diagnosis was. This means there was significant apprehension and anxiety to diagnosis of the disease. This aspect of patient could be improved via adequate counselling session by the treating physician. For hyperthyroid patients, initial diagnosis stress was comparatively more. Hypothyroid patients showed little low scores on changes in their appearance, depression and withdrawal from thyroid hormone. For Social concerns; very low score was seen in question to support they get; in both hyperthyroid and hypothyroid patients. Majority females feeling a lack of social support exemplifies the male dominated society in our country.

The physical domain was worst affected as it dealt with physical complaints faced by patients; among them fatigue had least score which was significant as it was a common chief complaint seen in both groups; this result is similar to study by Klaver E.L., et al [16]. Cross-sectional study by C Shivaprasad., et al. evaluated 244 hypothyroidism patients with SF-36 questionnaire. The patients' data were compared to 250 age and sex-matched healthy controls and found that patients with hypothyroidism had significantly lower scores. Hypothyroidism is associated with reduced QOL among Indian patients. This is in accordance with our study, where Hyperthyroid patients showed better QoL than hypothyroid in all domains, however, difference was not statistically significant. They generally experienced greater reductions in physical dimensions than social and emotional dimensions [17].

High adherence was seen in 68.75% hyperthyroid and 69.14% hypothyroid patients. Hypothyroid patients had marginally high adherence to medication than hyperthyroid patients, which was similar to a study done by Cappelli., et al [18]. Low adherence could be due to side effects of carbimazole like skin reactions, arthropathies, agranulocytosis, upset stomach etc [19]. Hypothyroid patients were adherent more as levothyroxine is easily administered and evaluated, well tolerated, and contains a single oral dose regime. Studies by MMAS-8 questionnaire found high adherence to Levothyroxine treatment for both tablet and liquid formulations. Taking Levothyroxine before breakfast on empty stomach was most convenient for patients. A study by Carlo Cappelli., et al. of 320 patients (272 female), median age 47.9 ± 15.6 years (range, 20 - 78 years) 87% of the participants were adhering to treatment for both formulations [18].

A significant positive correlation between spiritual domain score with both occupation and adherence was found. This could mean that as a person accepts the diagnosis and starts looking for positive changes the illness has brought, his/her adherence to medication improves. Similarly, patients employed in skilled profession could better understand importance of adherence to treatment. We also observed a significant negative correlation between age and physical score, more so in hypothyroid patients. Age had a significant negative correlation with physical domain and GrandQoL scores, signifying that with increasing age physical symptoms like fatigue, joint pain, appetite changes etc have a negative impact on QoL of patients.

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Strengths of the Study

This study was an attempt to address the knowledge gap in prescription patterns, QoL, as well as the adherence to treatment amongst Indian population suffering from thyroid disorders. It analyzed the correlation of patient demographics with QoL and adherence.

Limitations of the Study

This was a cross-sectional study but if we had follow-ups, it would have yielded changes in QoL reflected as success in drug therapy. A comprehensive idea regarding spectrum of side effects with thyroid medications was missing and future studies can be planned in this direction. Our study was based in out-patient department, so we could not evaluate the spectrum of severity of hypothyroidism (myxedematous crisis) and hyperthyroidism (thyroid storm) and their effects on QoL. Also, we did not take into account duration since thyroid dysfunction and duration since start of treatment, which could have affected QoL as well as adherence.

Conclusion

We conclude that levothyroxine was prescribed for all the patients with hypothyroidism and carbimazole for nearly all the of patients with hyperthyroidism. In our study, Hyperthyroid patients showed better QoL than hypothyroid in all domains, however, difference was not statistically significant. Patients were quiet adherence to these treatment regimens and experienced an above average quality of life. As age increases, QoL of thyroid patients decreases. However, a positive outlook towards life can foster adherence.

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Conflict of Interest

Nil.

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