

# Assessment of Cost of Illness and Satisfaction with Life in Hypothyroidism Patients at Tertiary Care Centre, Erode- A Prospective Observational Study

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## ABSTRACT

**Background:** Recent research has highlighted the significant economic burden associated with hypothyroidism, showing that individuals affected by this condition experience increased healthcare costs due to both acute and chronic complications. This study aims to analyze the financial impact of treating hypothyroidism and to gauge the life satisfaction levels of patients undergoing treatment at a specialized hospital. **Materials and Methods:** This prospective observational study was conducted at a tertiary care hospital in Erode, Tamil Nadu, spanning 9 months from August 2023 to April 2024. The study enrolled 175 adult patients diagnosed with hypothyroidism who visited the outpatient department, excluding pregnant and lactating women, pediatric patients and those with irregular treatment adherence. Statistical analysis was performed using SPSS software with Student's *t*-test and Paired *t*-test methods. **Results:** Females showed a higher prevalence of hypothyroidism than males, particularly among housewives. Around 42.86% of participants had a family income ranging from 20,000 to 30,000 rupees. The primary medication prescribed to most participants was Thyroxine 100 mcg. Initial visits incurred higher costs compared to subsequent ones, with direct costs comprising over 50% of the total expenditure. Before intervention, most participants were somewhat dissatisfied with treatment, but after intervention, they were generally more satisfied. **Conclusion:** The study found that participants initially expressed moderate dissatisfaction with their treatment. However, following the intervention, there was a notable increase in satisfaction, evident from significant improvements in their Satisfaction with Life Scale (SWLS) scores, highlighting an overall enhancement in their quality of life.

**Keywords:** Direct cost and Indirect cost, Hypothyroidism, Intervention.

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## INTRODUCTION

Hypothyroidism manifests in a wide range of clinical presentations, from severe myxedema and multisystem failure to asymptomatic or subclinical forms where thyroxine and triiodothyronine levels are normal, but serum thyrotropin is slightly elevated.<sup>1</sup> This chronic condition involves insufficient production of thyroid hormones, leading to symptoms such as slow movements, reduced metabolism, cold intolerance, fatigue, hoarseness, weight gain and constipation. Cognitive impairments like decreased attention and memory issues can also occur.<sup>2</sup> In developed countries, hypothyroidism affects about 4-5% of the population, while subclinical hypothyroidism affects 4-15%. This condition is linked to various adverse health

outcomes, ranging from mild to severe.<sup>3</sup> The rising demand and cost of healthcare globally are driven by advancements in medical technology. Pharmacoeconomics, which involves evaluating both the costs and outcomes of therapeutic decisions, plays a crucial role in healthcare planning and prioritization. It allows for the comparison of drugs with varying costs and outcomes. Various pharmacoeconomic assessment methods, such as cost-effectiveness analysis and Cost of Illness (COI), are used based on the desired outcomes and specific interventions targeted.<sup>4</sup>

The growing recognition of hypothyroidism's impact on healthcare expenditures is evident. Recent studies indicate that individuals with hypothyroidism are more prone to acute and chronic complications, leading to higher hospitalization and drug costs. The additional expenses are largely attributed to increased hospital admissions, expensive outpatient treatments, higher nursing home care costs and escalated drug usage. To date, there has been no study conducted specifically on the cost of illness in



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hypothyroidism patients. The primary objective of this study is to evaluate the cost of illness for hypothyroidism treatment and to assess the overall life satisfaction of patients receiving care at a tertiary care hospital

## MATERIALS AND METHODS

**Study design:** Prospective observational method.

**Study site:** Tertiary Care Hospital, Endocrinology Department, Erode, Tamil Nadu.

### Ethical approval

This study was approved by the Annai JKK Sampoorani Ammal College of Pharmacy's Ethical Committee following the submission of a comprehensive proposal containing the study title, duration, inclusion and exclusion criteria, objectives and a concise methodology outlining the planned work.

**Study duration:** 9 months, from August 2023 to April 2024.

**Sampling method:** Convenience sampling.

**Sample size:** This study includes 175 patients diagnosed with hypothyroidism.

### Inclusion criteria

Patients visiting the outpatient department diagnosed with hypothyroidism, aged between 18 and 65 years and patients with additional co-morbidities. The patient who gave informed consent.

### Exclusion criteria

Pregnant and lactating women, pediatric patients, individuals with irregular treatment adherence and patients with complications such as atrophic thyroiditis, Hashimoto's thyroiditis, goiter and postpartum thyroiditis.

### Data entry form

A specifically designed data entry form was employed to input patient information including age, gender, medical history, occupation, co-morbid conditions, clinical data, thyroid complications and treatment medications. The gathered data underwent analysis and a report based on the findings was subsequently submitted.

### Data procurement

All relevant and applicable information was gathered using a specialized data entry form and Google Forms while patients awaited their appointments with the Endocrinologist. Ethical approval for the study was obtained from the institutional ethics committee. Anonymity and confidentiality of patient information were rigorously maintained throughout and after the study.

## Cost analysis

The direct expenses associated with anti-thyroid drugs were assessed and evaluated by the National Pharmaceutical Pricing Authority (NPPA) in India. These costs were presented both as total sums and as average values, using Indian Rupees (INR) as the currency reference.

## Satisfaction with Life Scale

The Satisfaction with Life Scale (SWLS) is a commonly employed self-assessment tool designed to gauge an individual's general satisfaction with life. Developed by Ed Diener and colleagues in 1985, the scale consists of 5 items. In this study, the SWLS was utilized to assess patients' life satisfaction in relation to hypothyroidism symptoms at two separate time points spaced 6 months apart.

## Total score means

31-35=Extremely satisfied,

26-30=Satisfied,

21-25=Slightly satisfied,

20=Neutral,

15-19=Slightly dissatisfied,

10-14=Dissatisfied,

5-9=Extremely dissatisfied.

## Study procedure

The study involved assessing patient healthcare costs over a six-month hospital visit period. Patient life satisfaction (Annexure-I) was measured using a 5-questionnaire set on a 7-point Likert scale, conducted in two phases: before and after counseling. Before counseling, SWLS scores were gathered from patients, while after counseling, post-counseling SWLS scores were obtained. Counseling was facilitated through pamphlets focusing on lifestyle modifications, based on previous research

**Table 1: Occupation based distribution.**

Occupation	Total number of participants	Percentage of participants
Housewife	61	37.89
Student	29	18.01
Weaver	17	10.56
Teacher	16	9.94
Office worker	14	8.70
Shopkeeper	11	6.83
Others	13	8.07
Total	161	100

Others-Nurses, Farmers, Cook, Retired, Daily wages, Watchman.

targeting hypothyroid patients. Lifestyle modification points listed in the Annexure-II.

### Statistical Analysis

The statistical analysis was carried out by using the SPSS software by the "Student *t* test" and "Paired *t* Test" method.

### RESULTS

Initially, our study included 175 patients. However, during the follow-up period, 14 patients were excluded for reasons such as irregular follow-up, changing hospitals and changes in illness status. Consequently, our study ultimately consisted of 161 patients, with 86.96% of them being female.

Figure 1 indicates that the majority (47.83%) of the patients in the study are within the age range of 26 to 45 years, followed by 29.19% of patients who fall within the 46 to 59 years age group. Table 1 reveals that the majority (37.89%) of the patients were housewives, while the smallest group (8.07%) fell into the "others" category. Regarding income, most patients (42.86%) fell into the 20,000 to 30,000 rupees, while the lowest percentage (13.04%) had incomes between 30,000 to 40,000 rupees. According to Figure 2, the majority of participants in our study used Thyroxine sodium for the treatment of hypothyroidism, specifically Thyroxine

sodium 100 mcg. As shown in Table 2, the average costs per person for the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> visits were 1560.63 INR, 1555.16 INR and 1512.42 INR, respectively. The largest portion of the costs was attributed to lab fees, with medicines accounting for the smallest percentage of expenditure.

Table 3 shows that initially, most patients were categorized as slightly dissatisfied before counseling. However, after counseling, the majority of patients were categorized as slightly satisfied. Table 4 reveals a statistically significant difference in participants life satisfaction before and after counseling.

### DISCUSSION

Various studies have projected that approximately 42 million individuals in India suffer from thyroid diseases.<sup>5</sup> Research from Mumbai indicates that congenital hypothyroidism is more prevalent in India, affecting 1 in every 2,640 newborns, in contrast to the global average of 1 in 3,800. A clinic-based study in Mumbai examined 800 children with thyroid disorders, finding that 79% had hypothyroidism. The primary causes of hypothyroidism in these children included thyroid dysgenesis, dyshormonogenesis and thyroiditis.<sup>6</sup> Among adults, the prevalence of hypothyroidism was examined in a population-based study conducted in Cochin, which included 971 participants. This study revealed

**Table 2: Cost based categorization among participants on 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> visit.**

Visit	Category		Sum of cost	Average cost per person	Percentage cost per person
1 <sup>st</sup> Visit	Direct cost	Drug cost	13121	81.49	5.22
		Consultation fee	48300	300	19.22
		Lab fee	81830	508.26	32.57
	Indirect cost	Transport	27680	171.93	11.02
		Food	23180	143.98	9.23
		Loss of pay	57150	354.97	22.75
	Total cost		251261	1560.63	100
2 <sup>nd</sup> Visit	Direct cost	Drug cost	13121	81.49	5.24
		Consultation fee	48300	300	19.29
		Lab fee	81530	506.4	32.56
	Indirect cost	Transport	27330	169.75	10.92
		Food	22950	142.55	9.17
		Loss of pay	57150	354.97	22.83
	Total cost		250381	1555.16	100
3 <sup>rd</sup> Visit	Direct cost	Drug cost	13042	81	5.36
		Consultation fee	48300	300	19.84
		Lab fee	74780	464.47	30.71
	Indirect cost	Transport	27530	170.99	11.31
		Food	22700	140.99	9.32
		Loss of pay	57150	354.97	23.47
	Total cost		243502	1512.42	100

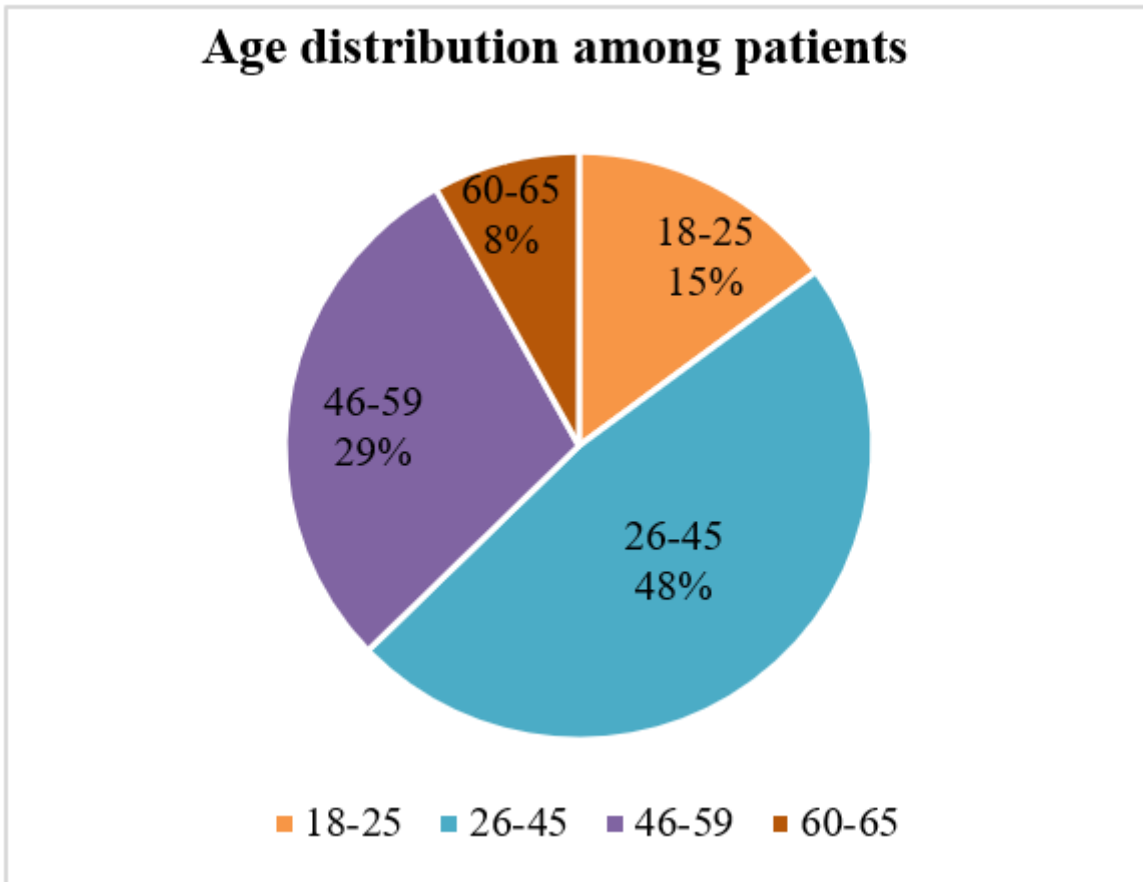


Figure 1: Age distribution of patients.

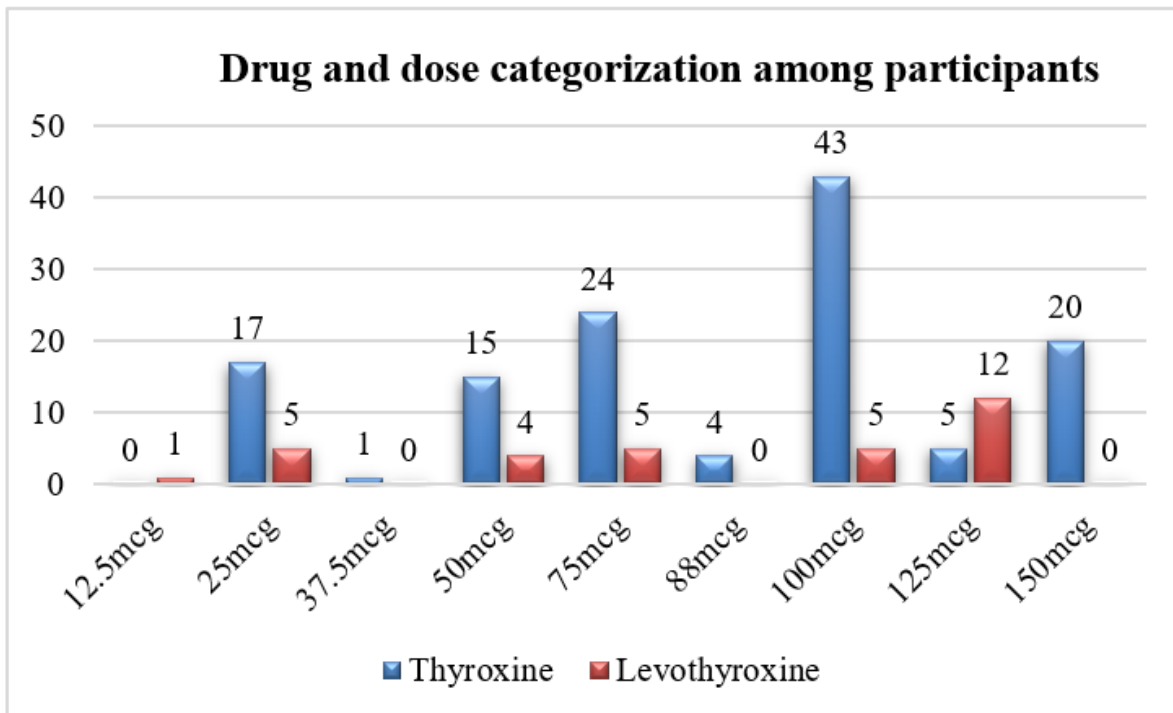


Figure 2: Drug and dose categorization among participants.

**Table 3: Categorization of overall SWLS score before and after intervention.**

Intervention	Gender	Extremely satisfied	Satisfied	Slightly satisfied	Neutral	Slightly dissatisfied	Dissatisfied	Extremely dissatisfied
Before	Male	3	1	4	2	7	4	0
After		3	4	7	4	5	4	0
Before	Female	13	18	28	18	30	21	12
After		16	22	30	14	25	16	11
Before	Total	16	19	32	20	37	25	12
After	Total	19	26	37	18	30	20	11

**Table 4: Paired sample t-test on satisfaction of treatment.**

Satisfaction	Mean	Sd	Std.error	p-value
Before Counselling	4.03	1.762	0.139	<0.001* (Statistically significant)
After Counselling	3.73	1.785	0.141	

that 3.9% of the adult population had hypothyroidism, while 9.4% had subclinical hypothyroidism. Women exhibited a higher prevalence of hypothyroidism (11.4%) compared to men (6.2%).<sup>7</sup>The study results indicated that hypothyroidism is more prevalent in women than in men. This finding aligns with the study by Unnikrishnan AG *et al.*, which also concluded that women are more frequently affected by hypothyroidism.<sup>8</sup> Autoimmune diseases are more prevalent in women, likely due to the influence of sex steroids on the immune system. Although not fully understood, estrogen and progesterone seem to affect the differentiation and maturation of lymphocytes and play a role in triggering autoimmune responses.<sup>9</sup> The study revealed that individuals aged 26-45 are most commonly affected by hypothyroidism. This observation is consistent with findings by Unnikrishnan AG *et al.*, who determined that the 18-35 age groups is also frequently impacted by this condition.<sup>8</sup>This study has indicated that hypothyroidism is prevalent among housewives, potentially due to gender differences and hormonal imbalances. Another study similar these findings, showing a high rate of thyroid disease in housewives.<sup>10</sup> In terms of income, the majority of patients (42.86%) reported earning between 20,000 and 30,000 rupees, while the smallest percentage (13.04%) had incomes ranging from 30,000 to 40,000 rupees. Furthermore, a study by Mandal RC *et al.* revealed that individuals with a monthly family income of less than 10,000 rupees are more likely to suffer from hypothyroidism.<sup>11</sup>In our study, the majority of patients were treated with Thyroxine, which is widely recognized as the standard therapy for hypothyroidism. Levothyroxine remains the cornerstone of hypothyroidism management and is listed among the World Health Organization's essential medicines necessary for fundamental healthcare.<sup>12</sup> This study concluded that the direct treatment costs for hypothyroidism are 55% higher than the indirect costs. On average, laboratory expenses per person were 500 rupees, while consultation fees averaged 300 rupees. In the year 2021, a study by Hepp Z. *et al.* involving hypothyroid patients, the annual laboratory costs were found to be \$6.14 per person, with

drug-related expenses averaging \$207.43 per person per year. The total estimated cost for hypothyroid patients was \$460.20. The analysis also identified an additional \$171 in annual absenteeism costs per patient. Overall, the annual medical expenses for each hypothyroid patient in the United States range between \$460 and \$2,555.<sup>13</sup>According to the Endocrine Society (2015), the average cost of treating thyroid disease was \$343, with outpatient visits averaging \$409 and prescription drugs costing \$16.21.<sup>14</sup> In a 2020 study by Sahara *et al.* on hyperthyroidism patients, it was found that most participants were housewives. The average doctor consultation cost was 69,347.83, the average laboratory cost was 465,683.70 and the average drug cost was 14,347.83. This study also revealed that laboratory costs comprised 83% of the total medical expenses.<sup>15</sup> Vadziuk *et al.* (2013) reported that the annual direct costs of treating hypothyroidism per patient were \$229.10, with indirect costs at \$639.16, leading to a total 12-month Cost of Illness (COI) per patient of \$868.26.<sup>16</sup>According to our findings, direct costs were the highest expenditure. A study by Hyun KR *et al.* (2014) on Korean thyroid patients concluded that 75.1% of costs were direct, while 24.9% were indirect.<sup>17</sup> However, another study found that indirect costs were the highest expenditure for hypothyroid patients.<sup>16</sup>Our study findings revealed a statistically significant disparity before and after the intervention. Samuels MH *et al.* conducted a study where patients exhibited marked improvements in various SF-36 scales following six months of levothyroxine therapy, specifically in role vitality, bodily pain, physical functioning, social functioning and mental health. Similarly, a crossover trial demonstrated varying SF-36 scores across baseline, euthyroid and subclinical hypothyroid phases.<sup>10</sup>In our study, we noted significant variations in SWLS scores post-intervention. Ortega *et al.* (2016) assessed the psychometric attributes of the Satisfaction with Life Scale in Mexican adults, underscoring notable distinctions between the health statuses of the 2 groups.<sup>18</sup>This study is constrained by several limitations include it is a single-center study, the study population size is small, it does not encompass thyroid patients

with other concurrent conditions and the duration of the study period is limited. One of the strengths of this study lies in its pioneering approach, being the first to comprehensively examine both direct and indirect costs among hypothyroid patients. Moving forward, future research could enhance its impact by conducting a multicenter study. This would involve comparing Complete Blood Count (CBC) and Thyroid Function Test (TFT) levels across four distinct patient groups: those receiving Thyroxine with intervention, Thyroxine without intervention, Levothyroxine with intervention and Levothyroxine without intervention.

## CONCLUSION

The study found that hypothyroidism is more common in females, particularly housewives. Most participants had a family income of 20,000 to 30,000 rupees. Thyroxine 100 mcg was the most frequently prescribed medication. Initial visit costs were higher than follow-ups, with lab fees being the largest expense. Drug costs were lower in comparison. Patient satisfaction and quality of life improved post-treatment, reflected in higher SWLS scores.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ETHICAL STATEMENT

Ethical number is EC/M.Pharm/2023-04.

## ABBREVIATIONS

**CBC:** Complete blood count; **COI:** Cost of illness; **SWLS:** Satisfaction with Life Scale; **TFT:** Thyroid function test.

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## ANNEXURE – I

**ASSESSMENT OF SATISFACTION WITH LIFE AMONG PATIENTS WITH HYPOTHYROIDISM****Instructions:**

Below are five statements that you may feel satisfied or dissatisfied with. Indicate your agreement with each item by tapping the appropriate box, from Extremely Satisfied to Extremely dissatisfied. Please be open and honest in your responding.

Patient name:

Age:

Gender:

S.NO	QUESTIONS	SCORES						
		Extremely Dissatisfied (1)	Dissatisfied (2)	Slightly dissatisfied (3)	Neutral (4)	Slightly satisfied (5)	Satisfied (6)	Extremely Satisfied (7)
1	Are you satisfied with the current treatment for your under active thyroid condition?							
2	Are you satisfied in your life with your illness and symptoms?							
3	How convenient are you to follow your treatment for under active thyroid?							
4	Do you feel that current treatment is controlling your symptoms of under active thyroid?							
5	Rate your overall energy levels and your ability to manage your daily routine since being diagnosed with hypothyroidism							

**ANNEXURE - II**

Life style modification Pamphlet

***Hypothyroidism***

Hypothyroidism is characterized by an underactive thyroid gland, which is responsible for producing hormones that regulate various bodily functions. Thyroid gland doesn't produce enough thyroid hormones, leading to a slowdown in metabolism and affecting many organs and systems in the body.

***Etiology***



Autoimmune Thyroiditis



Radiation Therapy



Thyroid Surgery



Inflammation



PITUITARY DISORDERS

***Life style modification***



Exercise



Sleep well



Use medication properly



Regular check-up



Avoid smoking



Avoid alcohol

***Food to eat***



Lentils and pulses



Iodized salt



Sea food



Citrus fruit



Barley, wheat

***Food to avoid***



Soya based product



Fast food

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