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Original Article

Effect of *Barg-e-Sehjana* (*Moringa oleifera* Lam.) on Hypothyroidism: A Randomized Single Blind Placebo Controlled Clinical Study

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Abstract

Background: Hypothyroidism is a widely prevalent endocrine disorder that can result in multisystem dysfunction and end-organ damage if left untreated. In conventional medicine, levothyroxine remains the standard therapy; however, it may be associated with adverse effects such as iatrogenic hyperthyroidism, osteoporosis, increased risk of fracture, and atrial fibrillation.

Objectives: The present study was designed to evaluate the therapeutic potential of *Moringa oleifera* Lam. (*Barg-e-Sehjana*) in the management of hypothyroidism.

Methods: In this randomized single blind placebo controlled clinical study, a total of 52 patients diagnosed with hypothyroidism were randomly assigned into two groups: test (n=26) and control (n=26). The test group received *M. oleifera* Lam. powder at a dose of 3 g/day, while the control group received placebo at a dose of 3 g/day with water once a day after breakfast for 45 days. Out of 52 patients, 46 patients completed the study, and their serum TSH levels were determined at baseline and at the end of the trial as a study outcome.

Results: In the test group, the mean baseline TSH level decreased from 10.22±3.72 µIU/mL to 6.83±2.85 µIU/mL. The difference was 3.39, with a *P* value of <0.001 and Cohen's d of 3.9, indicating a large effect size with a 95% confidence interval. In contrast, the control group exhibited a less significant reduction from 8.21±3.22 µIU/mL to 6.38±4.84 µIU/mL with a difference of 1.83 (*P*<0.10).

Conclusion: The findings of the present study demonstrate that the daily administration of 3 g of *M. oleifera* Lam. powder is effective in reducing elevated levels of TSH and improving thyroid function in patients with hypothyroidism.

Keywords: Hypothyroidism, *Barg-e-Sehjana*, *Moringa oleifera* Lam., TSH

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Background

Thyroid disorders are the most prevalent endocrine disorders globally (1), with hypothyroidism representing the most common pathological hormone deficiency. Hypothyroidism is defined as a biochemically reduced level of circulating thyroid hormones (primarily free T_4) along with elevated serum thyroid-stimulating hormone (TSH) levels exceeding the normal range (2). The global prevalence of hypothyroidism in developed countries is estimated to be approximately 4%-5%, whereas the prevalence is significantly higher in India, affecting nearly 11% of the population (3). It is estimated that approximately 42 million individuals in India suffer from various forms of thyroid disease, with hypothyroidism being the most prevalent (4). The disorder disproportionately affects females; in other words, it is approximately 5-8 times more common in females than males (5). It arises due to various etiologies and presents with a wide range of clinical manifestations when the concentration of circulating thyroid hormones becomes insufficient to support normal metabolic functions, clinical hypothyroidism occurs (6). The condition ranges from subclinical or asymptomatic presentations to severe cases, including multisystem failure and coma (7). Globally, iodine deficiency remains the leading cause of hypothyroidism (8). Other notable etiologies include chronic autoimmune thyroiditis (Hashimoto's thyroiditis), therapeutic interventions such as radioactive iodine treatment or thyroidectomy, and adverse effects of certain medications including anticancer agents (e.g., ipilimumab, pembrolizumab,

nivolumab), amiodarone, lithium, and tyrosine kinase inhibitors. Transient hypothyroidism may also occur due to conditions like silent thyroiditis, subacute thyroiditis, and postpartum thyroiditis (9,10). Hypothyroidism is classified into three types: primary hypothyroidism, which results from intrinsic thyroid gland dysfunction and is characterized by elevated TSH and reduced free T_4 levels; secondary hypothyroidism, due to anterior pituitary dysfunction, results in inadequate TSH secretion (11); tertiary hypothyroidism, also known as hypothalamic hypothyroidism, is attributed to deficient secretion of thyrotropin-releasing hormone (TRH) by the hypothalamus (12).

The clinical burden of hypothyroidism is considerable, if left untreated, and it is associated with significant reduction of quality of life, increased morbidity, high mortality, and increased number of sick leave days (13). Long-term complications include anemia, hypertension, hypercholesterolemia, hyperlipidemia, type 2 diabetes mellitus, obesity, myopathy, migraine, depression, and anxiety (14). Hypothyroidism can lead to impaired visuomotor and visuospatial skills, delayed speech and language development, cognitive deficits, and attention disorders in children. In adults, prolonged hypothyroidism has been associated with increased risk of developing neurodegenerative disorders such as Parkinson's and Alzheimer's disease (15), as well as an increased risk of heart failure (16). The current standard treatment for hypothyroidism is lifelong monotherapy with levothyroxine (LT_4), a synthetic form of the endogenous T_4 hormone (17). Management strategies are guided by the degree of TSH elevation and the severity of symptoms (18). However, long-term levothyroxine therapy is associated with adverse effects, which include osteoporosis, increased risk of fractures (19), atrial fibrillation, ischemic heart disease, myocardial infarction, and hypocortisolemia (20). Furthermore, levothyroxine absorption may be compromised in patients with *Helicobacter pylori* infection, autoimmune gastritis, and gastroparesis, as well as those who have undergone gastric sleeve surgery or other bariatric surgery. Concomitant use of medications such as statins, proton pump inhibitors, calcium, and iron supplements may also impair its bioavailability (21). The limitations and side effects of conventional pharmacotherapy have prompted growing interest in complementary and alternative medicine. Herbal medicines, rooted in traditional medical systems, are increasingly being explored for their potential to offer causative and holistic approaches with minimal side effects. These alternative therapies may provide new insights into more sustainable and personalized management of hypothyroidism.

Unani literature highlights that the manifestations associated with the *Su'-e-Mizaj Bārid Balghami* (deranged phlegmatic temperament) closely resemble the clinical picture of contemporary hypothyroidism such as *Farbahi* (weight gain), *Adam tahmil al-barid* (cold intolerance), *kasrat-e-naum* (excessive sleep), *Nisyan* (dementia), *Qabz* (constipation), *Kahili* (lethargy), and *Khafqan* (palpitation). Treatment in the *Unani* system involves both single drugs and compound formulations. Single drugs are selected based on their intrinsic *Mizāj* (temperament) to counteract the *Su'-e-Mizaj* (altered temperament) of underlying disease pathology (22).

In *Unani* medicine, hypothyroidism is managed using various single drugs such as *Ashwangandha* (*Withania somnifera* L.), *Barhami* (*Bacopa monnieri* L.), *Darchini* (*Cinnamomum zeylanicum* L.), *kalonji* (*Nigella sativa* L.), *Jadwar* (*Delphinium denudatum Wall*), *Kachnal* (*Bauhinia purpurea L.*), *Muquil* (*Commiphora mukul*), *Sarakhs* (*Dryopteris filix-mas* L.), and *Siras* (*Albizia lebbeck* L.) and compound formulations such as *Majoon-e-Sarakhs*, *Majoone-Atiyab, Habb-e-Muquil, Habb-e-Asgand, Jawarish Jalinus, Jawarish Bisbasa, Safoof Darchini, Majoon Qaranfal*, and so on (20,22).

Moringa oleifera Lam., a versatile medicinal plant belonging to the family Moringaceae, has been traditionally used for the treatment of various ailments, including hormonal disorders such as hypothyroidism, and is considered a good source of dietary elements such as proteins, essential amino acids, vitamins, and antioxidants (1,23). It is commonly referred to as the horseradish tree or drumstick tree. It is extensively cultivated and valued for its nutritional and therapeutic potential. Various parts of plants (e.g., leaves, seeds, and pods) are used both as food supplements and for medicinal purposes (24). Dried leaves and their extracts are especially noted for their health-promoting properties (25). The plant is rich in bioactive constituents, including flavonoids, phenolic acids, and alkaloids, which contribute to its pharmacological effects (26). Numerous studies have highlighted the broad spectrum of pharmacological activities of *M. oleifera* Lam., including antioxidant, anti-inflammatory, anticancer, antidiabetic, antihypertensive, neuroprotective, hepatoprotective, nephroprotective, anthelmintic, antimicrobial, hypocholesterolemic, and immunomodulatory effects. Based on its diverse pharmacological activities and preliminary findings from pilot studies, *M. oleifera* Lam. appeared to be effective in improving thyroid function (T_3, T_4, TSH) in individuals with hypothyroidism (20,27). Therefore, the present study was conducted to evaluate the therapeutic effect of *M. oleifera* Lam. in the management of hypothyroidism.

Materials and Methods

Study Design and Setting

This study was designed as a randomized single blind placebo-controlled clinical study to evaluate the therapeutic efficacy of *M. oleifera* Lam. in patients with hypothyroidism. The study was conducted at NIUM (National Institute of Unani Medicine), Bangalore, using a simple random sampling method.

Duration of Study

The study was conducted over a period of 8 months from June 23, 2021 to February 23, 2022. The diagnosis of hypothyroidism was confirmed based on elevated serum TSH levels.

Sample Size Calculation

Assuming a pooled standard deviation of 4.32 units for TSH, the study would require a minimum sample size of 26 for each group (i.e. a total sample size of 52, assuming equal group sizes) to achieve a power of 80% and a significance level of 5% (two-sided) for detecting a true difference in means between the test and the control group of 3.8 units (28).

Randomization

A randomization list was generated by the investigator. The patients were allocated to the test and control groups by a simple randomization technique using computer-generated randomization software (Experimental Design Generator and Randomizer).

Patients' Recruitment and Study Setting

Patient recruitment began on June 23, 2021, and a total of 52 patients were enrolled after getting written informed consent from the OPD/IPD of NIUM Hospital, Bangalore, India. The inclusion criteria and exclusion criteria for patient selection were as follows.

Inclusion Criteria

Patients with hypothyroidism were recruited in the study if they had met the following criteria:

1. Patients of any gender, either male or female
2. Age range of 20-60 years
3. Known cases of hypothyroidism with chronicity of 3-5 years
4. TSH level ranges between 6-20 µIU/mL
5. Patients who give consent and are able to follow the protocol

Exclusion Criteria

Patients were excluded if they had at least one of the following criteria during the intervention.

1. Patients with the TSH range ≤ 6 ≥ 20 µIU/mL
2. All complicated cases of hypothyroidism, recent thyroid surgery, or those who have received radioactive iodine treatment within 6 months
3. Pregnant and lactating women
4. Unable to give consent and follow the protocol

Study Drug

Collection and Identification of Test Drugs

The fresh leaf powder was procured from the local market of Bangalore, taxonomically identified and authenticated by the Curator of the Foundation for Revitalization of Local Health Traditions (FRLHT), Bangalore, with voucher number 5640.

Drug Dose and Dosage Form

Patients in the test group received *M. oleifera* Lam. powder at a dose of 3 g/day in the form of a capsule (4 capsules of 750 mg), while those in the control group received a placebo (wheat flour) 3 g/day in the form of a capsule (4 capsules of 750 mg) given by the investigator. Both interventions were administered daily after breakfast with water for a duration of 45 days. Follow-up evaluations were conducted on the 15th, 30th, and 45th days to assess treatment compliance and objective parameters, particularly changes in serum TSH levels, were monitored at baseline and post-treatment follow-up at the 45th day.

Statistical Analysis

Statistical analysis was conducted using SPSS software version 28.0 (IBM Corp., Armonk, NY). The Wilcoxon signed-rank test was used to analyze parameters within each group, while the Mann-Whitney U test was employed for comparisons of quantitative variables between the test and control groups. Qualitative variables were analyzed using the chi-square test and the independent samples *t*-test. Quantitative data were expressed as mean ± standard deviation (SD), while qualitative data were presented as frequency and percentage. Results with P value < 0.05 were considered statistically significant.

Results

Study Flow

A total of 100 patients were assessed for eligibility. Out of these patients, 48 were excluded, 40 did not meet the inclusion criteria, and 2 declined to participate. The remaining 52 patients were randomized equally into two groups, a test group (n = 26) receiving *M. oleifera* Lam. and a control group (n = 26) receiving placebo. A total of 46 patients completed the study, with 23 in each group. Six patients dropped out; three from the control group during the third follow-up, and three from the test group during the second and third follow-ups, citing personal reasons. The flow of patients through the study is illustrated in the CONSORT diagram (Figure 1).

Socio-demographic Data

The socio-demographic profile of the patients is summarized in Table 1, which includes age, gender, occupation, and educational status. The mean age of the patients was 36.8 ± 9.71 years. The study population was predominantly female (43, 93.5%), with only three male patients (6.5%). Hypothyroidism is significantly more common in females than in males, with multiple studies and authoritative health organizations confirming this disparity. The reasons include autoimmune predisposition, hormonal factors, and gender-specific immune function differences. The majority of patients were Muslim (35, 76%) and the rest were Hindu (11, 23%). Most patients reported mixed dietary habits (44, 95%) and 43 patients (93%) were married. Based on the results, 86% of them were housewives and 91% belonged to the

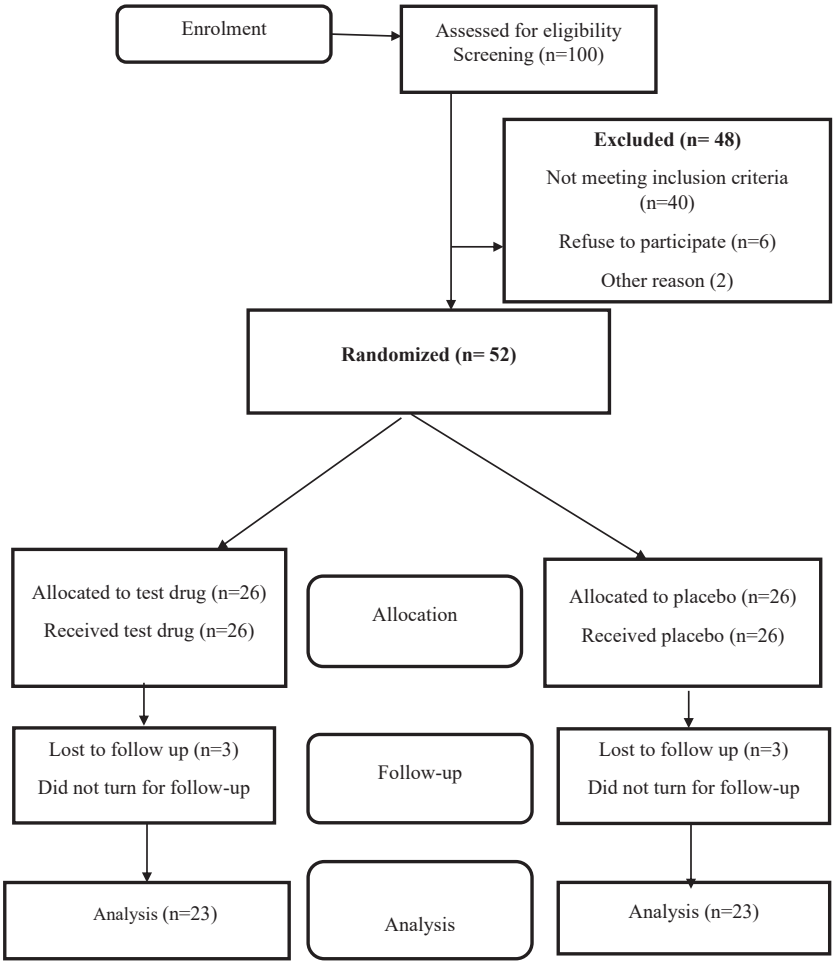

Figure 1. CONSORT Diagram (Flow Chart of the Study)

Table 1. Socio-demographic Data

Variables	Value
Age, Mean ± SD	36.8 ± 9.71
Gender (female/male)	43/3
Religion (Muslim/Hindu)	35/11
Marital status (married/unmarried)	43/3
Occupation (housewives/student/Imam/mechanic/tailor)	40/3/1/1/1
Socioeconomic status (upper middle class/upper lower class)	42/4
Dietary habit (mixed/vegetarian)	44/2
BMI, Mean ± SD	30.39 ± 6.26
Mijaz (Balgami)	46

BMI: Body mass index
The used test included chi-square test and independent samples *t*-test.

upper-middle socioeconomic class. In terms of body mass index (BMI), 19 (41%) had a BMI of 30-40 kg/m², while 15 (32%) had a BMI between 25 and 30 kg/m². Notably, all patients (46, 100%) were found to be *Balghami Mizaj* (phlegmatic temperament).

Primary Outcomes

The primary outcome was the change in serum TSH levels, detailed in Table 2. Test group, receiving *M. oleifera* Lam., demonstrated statistically significant reduction in TSH levels from a baseline mean of 10.22 ± 3.72 µIU/mL to 6.83 ± 2.85 µIU/mL. The difference was 3.39 with a *P* value of < 0.001 and Cohen's d of 3.9, indicating a large effect size with a 95% confidence interval. In contrast, the control group revealed a smaller and less significant reduction in TSH levels from 8.21 ± 3.22 µIU/mL to 6.38 ± 4.84 µIU/mL, with a mean difference of 1.83. These results suggest that *M. oleifera* Lam. has a significantly greater impact in lowering TSH levels compared to placebo.

Secondary Outcomes

Secondary outcomes, including safety parameters such as hemoglobin, total leukocyte count, erythrocyte sedimentation rate, aspartate aminotransferase, and alanine aminotransferase, were also assessed to monitor the tolerability of the drug (Table 3).

Discussion

Unani system of medicine is an ancient Greek holistic medicinal system with a history of 2500 years. The WHO has paid great attention to *Unani* medicine and has raised considerable awareness about the use of herbal medicine for some treatment purposes throughout the world (29).

Unani system is based on the theory of *Akhlāṭ-i-Arbaʿa* (four humors) and four *Mizāj* (temperaments), which form

Table 2. Primary Outcomes: Effects of Test Drug on Serum TSH Level

Variables	Before treatment (Mean ± SD)	After treatment (Mean ± SD)	Difference	*P*-value	Effect size (95%CI)
TSH (μIU/mL) Test group	10.22 ± 3.72	6.83 ± 2.85	3.39	($P < 0.001$)	3.9
TSH (μIU/mL) Control group	8.21 ± 3.22	6.38 ± 4.84	1.83	($P < 0.10$)	

SD: Standard deviation; CI: Confidence interval; TSH: Thyroid-stimulating hormone
P values obtained from the Wilcoxon signed rank test within the group. *P* values obtained from Mann-Whitney U test between the groups

Table 3. Safety Profiles: Comparative Assessment of Safety Profiles before and after Treatment

Safety variables	Before treatment (mean ± SD	After treatment (mean ± SD)	Difference	*P* value
Test group				
HB (g %)	12.03 ± 1.052	12.06 ± 0.947	-0.03	0.863
TLC (per mm^3)	7528 ± 2619	7482 ± 2148	46	0.614
ESR (mm/h)	20.95 ± 12.82	19.26 ± 13.93	1.75	0.240
AST (U/L)	24.21 ± 7.391	20.65 ± 6.478	3.65	0.0001
ALT (U/L)	34.91 ± 13.16	32.00 ± 11.87	2.91	0.200
Alkaline phosphatase (U/L)	100.39 ± 30.70	98.13 ± 28.69	2.26	0.435
Blood urea (mg/dL)	22.74 ± 9.05	22.47 ± 7.19	0.27	0.902
Creatinine (mg/dL)	0.89 ± 0.147	0.900 ± 0.085	-0.01	0.796
Control group				
HB (gm %)	12.44 ± 1.43	12.32 ± 1.28	0.12	0.337
TLC (per mm^3)	7733 ± 2428	7683 ± 1872	51	0.069
ESR (mm/h)	18.26 ± 10.67	16.60 ± 8.77	1.66	0.350
AST(U/L)	26.2 ± 11.98	27.82 ± 13.53	-1.62	0.0001
ALT(U/L)	37.34 ± 13.75	36.47 ± 16.55	0.87	0.669
Alkaline phosphatase (U/L)	107.17 ± 31.63	106.08 ± 30.27	1.09	0.709
Blood urea (mg/dL)	20.39 ± 4.17	21.30 ± 4.79	-0.91	0.392
Creatinine (mg/dL)	0.913 ± 0.148	0.8913 ± 0.141	0.02	0.547

Abbreviations: HB, Hemoglobin; TLC, Total leukocyte count; ESR, Erythrocyte sedimentation rate; AST, Aspartate aminotransferase; ALT, Alanine aminotransferase.

the foundation of diagnosis and treatment of the disease (30). In *Unani* literature, the condition known as *Sū'-i-Mizāj Bārid Balghamī* (cold phlegmatic derangement of temperament) presents with clinical features that closely resemble those of hypothyroidism described in modern medicine such as *Farbahi* (weight gain), *Adam tahmil al-barid* (cold intolerance), *kasrat-e-naum* (excessive sleep), *Nisyan* (dementia), *Qabz* (constipation), *Kahili* (lethargy), and *Khafqan* (palpitation). According to *Unani* principles, treatment is based on the concept of *Ilāj bi'l-Ḍidd* (therapy by contraries), whereby drugs are selected based on their temperament in opposition to the temperament of disease. *M. oleifera Lam*., known to possess a hot and dry temperament, is considered to be suitable for treating hypothyroidism due to its opposing qualities to the cold and moist temperament associated with hypothyroidism. Therefore, its use is consistent in hypothyroidism as per concept of *Ilāj bi'l-Ḍidd* (therapy by contraries) (31).

Based on the above-mentioned findings of the study, daily use of *M. oleifera* Lam. for a period of 45 days after breakfast leads to a significant improvement in thyroid function and a decrease in serum TSH level (Figure 2).

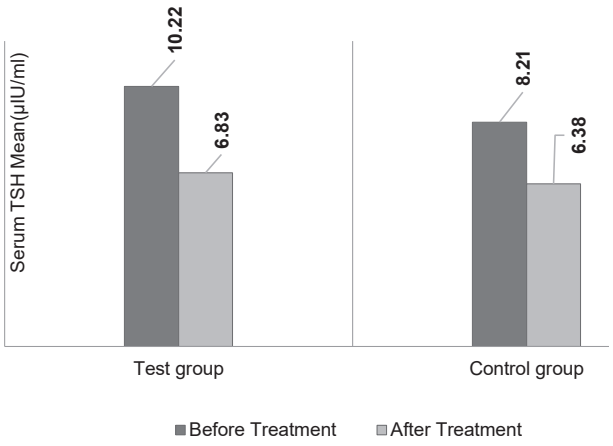

Figure 2 . Effects of Test Drugs on Serum TSH Level

Additionally, females are more frequently affected than males. This disparity is attributed to autoimmune predisposition, hormonal influences, and gender-specific immune function differences. It was found that serum TSH level significantly reduced at the end of the treatment in comparison with baseline findings, from a baseline

mean of 10.22 ± 3.72 μIU/mL to 6.83 ± 2.85 μIU/mL at the end of the study. The mean difference was 3.39, with a *P* value < 0.001 and a Cohen's d of 3.9, indicating a large effect size with a 95% confidence interval. In contrast, the control group revealed a smaller and less significant reduction in TSH levels from 8.21 ± 3.22 μIU/mL to 6.38 ± 4.84 μIU/mL, with a mean difference of 1.83 (*P* < 0.10).

The findings of this study are consistent with previous research conducted by Alam et al, demonstrating that the aqueous extract of *M. oleifera* Lam. significantly reduced serum TSH level and enhanced thyroid function, potentially through its anti-inflammatory, immunomodulatory, and antioxidant properties (21). Similarly, studies conducted by Moyo et al (32) and Ibrahim et al (33) revealed that the dried leaves of *M. oleifera Lam*. contain high levels of selenium (363 mg/kg) and zinc (13.03 mg/kg). These trace elements are beneficial for patients with hypothyroidism. It has been established that thyroid function is influenced not only by iodine but also by selenium, which plays a crucial role in the metabolism of thyroid hormones. Selenium is essential for the activity of iodothyronine deiodinase (selenoprotein), the enzyme responsible for converting thyroxine (T_4) to its active form, triiodothyronine (T_3). Additionally, selenium is vital for the function of glutathione peroxidase, an antioxidant enzyme that protects the thyroid gland from oxidative damage (34). Similarly, Panda and Kar demonstrated that the aqueous extract of *M. oleifera* Lam. exhibited significant anti-inflammatory activity. Additionally, several other medicinal plants have demonstrated antihypothyroid activity. For instance, *Commiphora mukul* has been reported to exert both anti-inflammatory and thyroid-stimulatory effects, primarily due to the presence of active constituents such as guggulsterone. This extract is known to stimulate thyroid function and increase the concentration of thyroid hormones, potentially ameliorating hypothyroidism (35).

Al-Hadidy and Dawood also demonstrated that *M. oleifera Lam*. was effective in improving experimentally induced hypothyroidism in a preclinical study. It was found to counteract elevated levels of visfatin, resistin, and tumor necrosis factor-alpha (TNF-α) by enhancing the production of thyroid-related hormones, specifically triiodothyronine (T_3) and thyroxine (T_4). Moreover, the anthocyanin compounds present in *M. oleifera* Lam. are reported to stimulate adiponectin production, which in turn promotes the synthesis of thyroid hormone, especially T_4, through a C-terminal globular reaction with receptors located in the mitochondria of thyroid gland cells (36).

The observed improvement in thyroid function following the administration of the test drug may be attributed to its anti-inflammatory, immunomodulatory, and antioxidant properties. These effects could have contributed to the regeneration of thyroid cells and the restoration of their normal physiological functions. This therapeutic potential is likely due to the presence of various bioactive phytochemicals and micronutrients, including flavonoids, phenolic acids, zinc, and selenium, as well as the antioxidant enzyme glutathione peroxidase. These constituents play a critical role in protecting the thyroid gland from oxidative damage and supporting the biosynthesis of thyroid hormones, particularly triiodothyronine (T_3) and thyroxine (T_4).

Future scope includes investigating the potential of *M. oleifera* Lam. in managing other thyroid-related disorders or as an adjunct to existing therapies in hypothyroidism, identifying active compounds in *M. oleifera* Lam. responsible for its thyroid-modulating effect, studying how genetic, dietary, and lifestyle factors influence individual responses to *M. oleifera* Lam. therapy, and developing standardized clinically validated formulations of *M. oleifera* Lam. for therapeutic use. Hence, this study may contribute to the development of novel therapeutic strategies for the treatment of hypothyroidism.

Limitations

This study should be replicated using more comprehensive study designs with a large sample size, longer duration of therapy, post-treatment follow-up, and revised and additional parameters like T_3, T_4, FT_3, and FT_4, as well as anti-thyroid antibodies, to further validate the efficacy of *M. oleifera* Lam.

Conclusion

This randomized, single-blind, placebo-controlled clinical study demonstrated that daily intake of 3 g of *M. oleifera* Lam. powder for 45 days significantly improved thyroid function in hypothyroid patients. The intervention was well tolerated with no adverse effects observed through the study. These findings suggest that *M. oleifera* Lam. may be considered a safe and effective treatment, either as monotherapy or as an adjunct to conventional hypothyroidism therapies.

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Authors' Contribution

Conceptualization: Mohd Aleemuddin Quamri.
Data curation: Shabnam Ansari.
Formal analysis: Shabnam Ansari.
Investigation: Shabnam Ansari.
Methodology: Mohd Aleemuddin Quamri.
Project administration: Shabnam Ansari.
Resources: Mohd Aleemuddin Quamri.
Software: Shabnam Ansari.
Supervision: Mohd Aleemuddin Quamri.
Validation: Mohd Aleemuddin Quamri.
Visualization: Mohd Aleemuddin Quamri.
Writing–original draft: Shabnam Ansari.

Writing–review & editing: Shabnam Ansari.

Competing Interests
The authors declare that they have no conflict of interests.

Ethical Approval
The study protocol was approved by the Scientific Review Committee and the Institutional Ethics Committee of the institute (IEC No: NIUM/IEC/2019-20/003/MOAL/03). The trial was registered at the Clinical Trials Registry of India (CTRI) under registration number CTRI/2021/04/033181. The trial was registered prospectively on 06/01/2021 and patient enrollment started on 23/06/2021.

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