International Journal of Community Medicine and Public Health
Iqbal A et al. Int J Community Med Public Health. 2023 Sep;10(9):3257-3263
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20232687

Original Research Article

Clinical study to evaluate the efficacy of *Commiphora muku* (Muqil) on thyroid function in hypothyroidism

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Received: 26 June 2023
Revised: 14 July 2023
Accepted: 18 July 2023

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ABSTRACT

Background: Hypothyroidism is a common endocrine disorder in which there is deficient production of thyroid hormone. Even though hormone replacement therapy is the mainstay treatment of hypothyroidism, but due to adverse effects on long term use, safe and effective Unani herbal drugs need to be researched. A decrease in serum concentrations of thyroid hormone causes an increased secretion of thyroid stimulating hormone (TSH), thus resulting in elevated serum TSH concentration.
Methods: The methods used to determine thyroid dysfunction are still serum thyroid stimulating hormone and the main circulating thyroid hormones thyroxine and triiodothyronine either as total or estimated free concentrations, and it is indeed the improved assay sensitivities and specificities that have made it possible to diagnose these milder forms. TSH, T3 and T4 with safety parameters tests were done before treatment and after completion of treatment in both the groups in order to make the proper diagnosis, to exclude other systemic ailments and to assess the efficacy/safety of the proposed herbal drug.
Results: The effects of test drug on lowering the raised serum TSH are attributed to the thyroid activities of the test drug which shoes highly significance $p<0.01$ before and after intervention. In respect of thyroxin there were no significant results between the test and control group.
Conclusions: The study concluded that the efficacy of *Commiphora mukul (*Muqil*)* on thyroid function was designed to explore the role of Unani herbal drugs in the management of hypothyroidism on Unani principles is effective, safe and cost effective.

Keywords: *Commiphora mukul* (Muqil), Hypothyroidism, Incidence, Thyroid hormone, Thyroid stimulating hormone

INTRODUCTION

The incidence of thyroid disorders in India is high, with hypothyroidism being a condition that is more common. Lack of thyroid hormone or resistance of the body tissue to thyroid hormone with respect to metabolic demand results in disorder called hypothyroidism. Thyroid hormone is required for the normal functioning of each and every tissue of the body. Hence, its deficiency manifests as multisystem involvement. The TSH is the most sensitive test to diagnose thyroid dysfunction. The combination of FT_4 and TSH appears to correctly establish both hypothyroidism and its cause in the majority of patients. An elevated TSH in the presence of a low FT_4 establishes thyroidal dysfunction and primary hypothyroidism. A low TSH in the presence of a low FT_4 suggests the presence of a pituitary cause and should prompt imaging of the sella.[1] An elevated TSH in the

presence of a normal FT4 suggests subclinical hypothyroidism.[2,3]

Estimates of incidence of hypothyroidism vary depending on the population studied.[4] Primary hypothyroidism indicates decreased secretion of thyroid hormone by factors affecting the thyroid gland itself.[5] The highest prevalence of hypothyroidism up to 13·1% is noted in people aged 46-54 years, with people aged 18-35 years being less affected up to 7·5%. In the United states 0.3% population have overt hypothyroidism and 4.3% have subclinical or mild hypothyroidism.[6,7] The incidence of hypothyroidism is higher among women, in the elderly, and in some ethnic and racial groups.[8-10] The incidence of hypothyroidism in India have a female to male ratio of 6:1. The prevalence of hypothyroidism in India is 11%, compared with only 2% in the UK and 4·6% in the USA. The thyroid gland secretes two significant hormones, thyroxin and triiodothyronine commonly called as T_4 and T_3 that has the profound effect of increasing the metabolic rate of the body.[11] Hypothyroidism can affect all organ systems ,and these manifestations are largely interdependent of the underlying disorder but are a function of the degree of hormone deficiency.[12] The clinical features include somnolence, fatigue, weight gain, cold intolerance, loss of appetite, constipation, hoarseness of voice, loss of libido, menorrhagia, polymenorrhea, dyslipidaemia, polyarthalgias, myalgias, decreased reflexes etc.[13-14.] Even though hormone replacement therapy with thyroxine has been proven effective in its management, but owing to adverse effects like myocardial infarction, adrenocortical insufficiency, congestive heart failure etc. is a challenge to its long term use. So safe and effective herbal drugs from Unani systems of Medicine (USM) need to be researched for its management. Hence, a single Unani drug, *Commiphora mukul (*Muqil*)* was selected which has shown positive thyroid activity in experimental studies to correct hypothyroid state.[15] Research has demonstrated that *Commiphora mukul (*Muqil*)* activates the production of thyroid hormones thyroxin (T_4), triiodothyronine (T_3), and improves hypothyroidism.[16,17] Its lipid lowering effect is also related to its thyroid activity. 2-Guggulestrone-a ketosteroid counteracts the thyroid suppressant activity of carbimazole. Its thermogenic effect helps in cold intolerance of hypothyroid patients.[18]

The present study was designed to evaluate the efficacy of the drug on thyroid function on modern scientific parameters.

METHODS

This was a randomized single blind standard controlled clinical study. This study was carried out at Regional Research Institute of Unani Medicine (RRIUM) Srinagar Jammu and Kashmir. Patients were enrolled from the out-patient department of RRIUM Srinagar on the basis of history, physical examination and investigations. Before starting the study, the research protocol was duly approved by Institutional Ethical Committee (IEC), RRIUM Srinagar as per the norms. Thereafter, the study was started from 01 September and the enrolment of patients was completed on 10 November 2018. The duration of study was 60 days in both the test and control groups. Patients were randomized into test and control groups by lottery method of randomization. Patients who were on any other drug (Allopathic, Ayurvedic, Unani etc.) for this disease were stopped 15 days before enrolling into the study and were not allowed to take any other drug for hypothyroidism during the study peroid.

Inclusion criteria

Clinically diagnosed patients of hypothyroidism, sex-male, female, transgender, patient in age group of 20 to 60 years and willingness to sign the informed consent, follow the protocol and participate in clinical trial voluntarily were included.

Exclusion criteria

Patients below 20 and above 60 years, pregnancy and lactation, patients on iodine containing vitamins or minerals, patients who have undergone thyroid surgery, taken radioactive iodine therapy, diabetes mellitus, renal dysfunction, patients who fail to give consent, all complicated cases of hypothyroidism, liver diseases, gastrointestinal diseases (peptic ulcer disease), IHD and hypertension, and patients not willing to be enrolled for the study were excluded.

Selection of cases

The source for selection of cases was the out-patient department of RRIUM Srinagar. History and clinical examination was the basis for enrolling patients for the study. Patients were asked complete history, present and past and general physical and systemic examinations were carried out. Specially designed case record forms were used for the recording of the details of the patients which included name, age, sex, address, occupation, marital status, socio economic status, dietary habits, educational background, income, chief complaints, history of present illness, past history, family history, treatment history etc. General examination include pulse, BP, temperature, respiratory rate, build, skin, hair, tongue, eyes, nails, legs and feet etc. Systemic examination was carried out to rule out any involvement of that particular system.

Particular attention was given to know about past history of other diseases like, diabetes-mellitus, hypertension, Addison's-disease, Cushing's-syndrome, PCOS, IHD, phaechromocytoma, liver, kidney, spleen, intestinal diseases etc. After history taking, a complete general and systemic examination was done for any findings. The patients were allotted into the test and the control groups as per the randomization and test as well as control drugs were advised accordingly.

Investigations

A set of investigations were carried out in all the patients to include or exclude from the study and to assess the efficacy and effect of test and control drug on different parameters which included complete blood counts (CBC), erythrocyte sedimentation rate (ESR), fasting blood sugar (FBS), lipid profile, liver function test (LFT), kidney function test (KFT), urine examination, ECG, thyroid function test (TSH, T_4, T_3). All the above mentioned investigations were carried out in all the patients before the commencement of the study and after the completion of the study.

Consent of the patient

Before enrolling the patients for the study, every patient was provided a set of specially designed Information Consent Form (ICF) which included all the relevant information about the study, investigations, drug, method of treatment and follow-up plan with all the options to ask any query regarding the study. After that when the patient signed the ICF, the treatment was started.

Sample size and allocation of subjects

A sample size of 40 subjects, 20 in each group was selected for the study. Simple random sampling (without respect) was used for allocation.

Assessment of Mizaj (temperament)

Temperament of each patient was assessed as per the specially designed scale before the start of treatment.

Follow-up plan for patients

Follow up was done on 15th day, 30th day, 45th day, 60th day in both the groups. On every follow up, patients were assessed for improvement of their symptoms or worsening of symptoms, appearance of any new symptom, adverse drug effects if any. All the clinical parameters were checked and were recorded in case record form (CRF).

Test drug

The test drug was a single *Unani* drug, *Commiphora mukul (*Muqil*).*

Control drug

Thyroxine sodium 50 mcg (Tab. Thyrox-50).

Method of preparation, dosage and mode of administration of test drug

The drug *Commiphora mukul* (Muqil*)* was purchased from market after inviting quotations from different suppliers by the purchase committee of Regional Research institute of Unani Medicine (RRIUM) Srinagar. The sample was duly identified by the expert for its originality. After proper cleaning, the drug was grinded into a granular powder from the Pharmacy Deptt. of Unani Medical College, Srinagar. The dosage of the test drug was 1 gm twice daily in the morning after breakfast and another dose in the evening to each patient with Luke warm water.

Dose and mode of administration of control drug

The control drug thyroxin sodium 50 mcg (tab. thyrox-50) was purchased from the market after inviting quotation from different suppliers by the purchasing committee of RRIUM Srinagar which was given as a single dose in the morning in control group patients. A total of 40 patients were enrolled for the study and were randomly grouped and were allocated either test (Group A) or control (Group B) groups in equal distribution. After the completion of treatment protocol of 60 days, statistical analysis was done. Group A was given Muqil *(Commiphora Mukul)* in the form of powder in the dose of 1 gm twice daily after breakfast and after evening tea with warm water for a period of 60 days. Group B were given tab. thyroxin sodium 50 mcg orally once a day for a period of 60 days. The patients of both groups were followed up after every 15 days for a period of 60 days and recording of improvement in subjective and objective parameters were done on case record forms (CRF).

Safety assessment

All the patients enrolled for the study were assessed for safety pre and post treatment protocol on following parameters; 1) Clinical check-up at every follow-up; 2) Complete Blood Picture like CBC, ESR, and Urine exam on pre (Day 0) and post treatment (Day 61) after completion of the treatment protocol; and 3) Blood sugar fasting, LFT, KFT, ECG were done before (Day 0) and after treatment (Day 61).

Statistical analysis

The recorded data was compiled and entered in a spread sheet and then exported to data editor of SPSS version 20.0, Minitab version 14, and Graph pad prism software's. The continuous variables like age and sex were expressed in terms of (mean ± standard deviation) and categorical variables were expressed in terms of frequency and percentage. Student's independent t-test was employed for inter-group analysis of continuous data and for intra-group analysis paired t-test was applied. Wilcoxon signed rank test was used for intra group analysis of ordinal data. Chi-square test and Fisher's exact test was employed for inter group analysis of categorical data and for intra- group (before vs after) analysis of data categorical, McNemar's test was applied. The graphical representation of data was presented by means of bar graph. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The maximum number of patients were found in the age group 41-50 years (33.3%), followed by 20-30 years (23.3%), 51-60 years (23.3%), 20-30 years (6%) in test group and 31-40 years 33.3%, followed by 41-50 years (33.3%), 51-60 years (26.7%), 20-30 years (6.7%) in control group.

Out of studied patients, 76.7% were females and 23.3% were males in test group and 80% were females and only 20% were males in control group.

Table 1: Age distribution among test group and control group (n=60).

Age (years)	Test group		Control		P value
	No	%age	No	%age	
20-30	7	23.3	2	6.7	0.5
31-40	6	20.0	10	33.3	
41-50	10	33.3	10	33.3	
51-60	7	23.3	8	26.7	
Total	30	100.0	30	100.0	
Mean±SD	38.47±11.25		40.23±9.91		

Table 2: Sex distribution among test group and control group.

Gender	Test group		Control		P value
	No	%age	No	%age	
Male	7	23.3	6	20.0	0.75
Female	23	76.7	24	80.0	
Total	30	100	30	100	
Test applied: Fisher's exact test					

Table 3: Comparison of tri-iodothyroxine among test group and control group.

Tri-iodothyroxine (T3)	Before treatment		After treatment		%change	P value
	Mean	SD	Mean	SD		
Test group	114.90	23.56	118.90	23.78	3.48	0.459
Control	105.51	24.60	113.10	14.84	7.19	0.055
P value (test group vs control)	0.55					

Table 4: Thyroxin among test group and control group.

T4	Before treatment		After treatment		Percent change	P value
	Mean	SD	Mean	SD		
Test group	7.20	1.506	7.10	1.93	1.38	0.808
Control group	7.14	2.08	7.37	1.48	3.22	0.533
P value (test group vs control group)	0.2874					

Table 5: Thyroid stimulating hormone among test group and control group.

									Significance of test group vs control group	
TSH	Test group				Control				P value	
	Before treatment		After treatment		Before treatment		After treatment		Before treatment vs before treatment	After treatment vs after treatment
	No	% age	No.	%age	No.	%age	No.	%age		
Normal	2.0	6.7	11.0	36. 7	2.0	6.7	10. 0	33. 3	1	0.786
Raised	28.0	93.3	19.0	63. 3	28. 0	93. 3	20. 0	66. 7		
Total	30.0	100.	30.0	100	30. 0	100	30. 0	100.0		

Continued.

				Significance of test group vs control group
TSH	**Test group**	**Control**		**P value**
Mean±S D =9.402±3.53	Mean±SD =7.93±4.37	Mean±SD =16.10±6.72	Mean±SD =7.55±4.705	
Test applied: Mcnemar, P- value= <0.001*		Test applied: Mcnemar, P- value = 0.004		

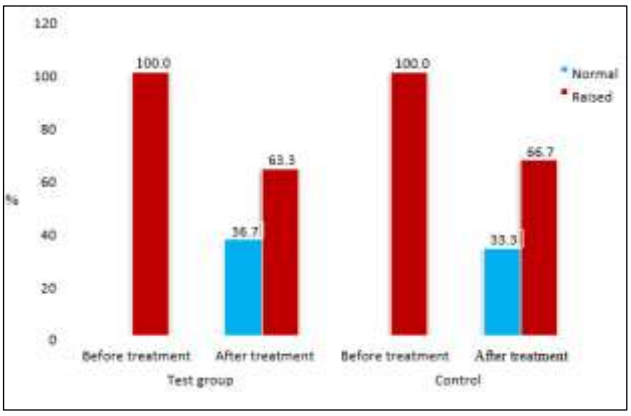

Figure 1: Percent change of thyroid stimulating hormone (tsh) among test and control groups.

DISCUSSION

The present study was conducted to evaluate the therapeutic efficacy of Unani drug *Commiphora mukul (*Muqil*)* on thyroid function in hypothyroidism.[20]

The Mean±SD for age of patients in test group was 38.4±11.25 and 40.23±9.91 in control group. The difference in age of patients in test and control group was not significant (p=0.5) using paired "t" test. The age were analysed in both the groups which showed that hypothyroidism in the age group 36-45 years (33.3%), 15-25 years (23.3%), 46-60 years (23.3%) and 26-35 years (20%). which shows that hypothyroidism is more prevalent in 3rd and 4th decade of life[21] (Table 1).

As far as the sex is concerned, the disease is more common in females with 76.6% females and 23.3% males in test group and 80% females with 24% males in control group which clearly indicates the highest incidence in females[22] (Table 2). This study shows that hypothyroidism prevails mostly in females. These data are in conformity with the findings reported in various clinical studies as far as the marital status of hypothyroid patients is concerned.[23,24]

The Mean±SD for T_3 in test group was 114.90±23.56 at baseline and 118.90±23.78 on 60th day, whereas in control group the Mean±SD score for T_3 was 105.51±26.40 at baseline and 113.10±14.84 at 60th day. When Mean±SD score for T_3 in both test and control group were compared statistically, it was found that the difference between the Mean±SD score for T_3 at 60th day compared with baseline was not significant (p>0.05) (Table 3). T3-predominant thyrotoxicosis, an entity that is less likely to achieve remission.[25] In some studies this entity is been reported to respond poorly to radioiodine, a phenomenon that may relate to rapid iodine turnover within the gland symptoms are typically mild, but rarely florid, transient thyrotoxicosis can be seen.[26] Serum T4 levels are proportionally higher than T3 levels, reflecting the ratio of stored hormone in the thyroid gland (in contrast to Graves' disease where T3 is often preferentially elevated).[27]

The Mean±SD for T_4 in test group was 7.20±1.506 at baseline and 7.10±1.93 on 60th day, whereas in control group the Mean±SD score for T_4 was 7.14±2.08 at baseline and 7.37±1.48 at 60th day. When Mean±SD score for T_4 in both test and control group were compared statistically, it was found that the difference between the Mean±SD score for T_4 at 60th day compared with baseline was not significant (p>0.05) (Table 4). Small changes in serum T4 and T3 concentrations, within the normal range, alter the serum TSH concentration, indicating that the inverse feedback relationship between serum free T4 and TSH applies across their normal ranges, as well as in disease states.[28,29]

The Mean±SD for TSH in test group was 9.40±3.53 at baseline and 7.93±4.37 on 60th day, whereas in control group the Mean±SD score for TSH was 16.10±6.72 at baseline and 7.55±4.705 at 60th day. When Mean±SD score for TSH in both test and control group were compared statistically using Mcnemar test, it was found that the difference between the Mean±SD score for TSH at 60th day compared with baseline was not significant (p>0.05). When the Mean±SD for TSH was compared with base line verses 60th day in test groups, it was highly significant (p=0.001) and in control group it was also significant (p=0.004) (Table 5 and Figure 1). These results coincide with the actions documented in various Unani classics and clinical studies.[30-33] The results indicated that both the test and control drugs are effective in reducing lethargy, weight gain, cold intolerance, puffiness of face and hoarseness of voice but the test formulation is more effective than the control drug.[35]

The effects of test drug on lowering the raised Serum TSH are attributed to the thyroid activities of the test drug. Scientific studies have demonstrated that *Commiphora mukul* (Muqil***)*** activates the production of thyroid hormones thyroxin (T_4), triiodothyronine (T_3), and improves the symptoms and signs of hypothyroidism.

Its lipid lowering effect is also related to its thyroid activity.2-guggulestrone-a ketosteroid counteracts the thyroid suppressant activity of carbimazole. Its calorific (thermogenic) effect helps in cold intolerance of hypothyroid patients.

There was no toxic effect of either test or control dug on safety parameters. So, it became evident that the test drug has significant effect on most of the subjective and objective parameters of hypothyroidism with no toxic effects on safety parameters. Therefore, the test drug *Commiphora mukul* ***(***Muqil***)*** is safe, effective, and economical and has wide pharmacological actions.

This study has few limitations. We looked at the time required to reach stable hypothyroidism patients, it is proposed the same trail may carry with large sample size (Phase-III) for generalise the efficacy of the proposed drug on large scale.

CONCLUSION

The test drug *Commiphora mukul (*Muqil*)* showed significant effect on TSH levels, which vindicated our hypothesis that the drug has effect in primary hypothyroidism. Hence, it can be concluded that the test drug has significant effect on objective parameters of primary hypothyroidism without having any toxic effect on any of the safety parameters. Hence the drug is safe and economical in the management of hypothyroidism.

Funding: The funds for the study were provided by Central Council for Research in Unani Medicine (CCRUM), Ministry of AYUSH, Govt. of India
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Iqbal A, Hanga AH, Zahoor S, Afzal A, Jan A, et al.. Clinical study to evaluate the efficacy of *Commiphora muku* (Muqil) on thyroid function in hypothyroidism. Int J Community Med Public Health 2023;10:3257-63.