

Effect of *Safoof-e-kalonji* (*Nigella sativa*) in the Management of Subclinical Hypothyroidism

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Abstract : **Background:** Thyroid disorders are the most common endocrine conditions encountered in clinical practice. The presentation of thyroid conditions can range from clinically obvious to clinically silent. In subclinical hypothyroidism, serum TSH levels are increased in clinically euthyroid patients with normal FT4 concentrations. Patients are usually asymptomatic or have minimal nonspecific symptoms that may be unrelated to hypothyroidism. The purpose of the study was to determine the effect of *Safoof-e-kalonji* for treating hypothyroidism.

Materials and Methods: A case series was conducted with Ten (10) patients of subclinical hypothyroidism, diagnosed on the basis of laboratory investigation of TSH Level. The value of TSH below 10mU/L with cardinal features of Hypothyroidism diagnosed as Subclinical Hypothyroidism.

Result: Patients with Subclinical hypothyroidism were significantly relieved in their signs and symptoms and decreased the level of TSH within in an average of 4 weeks treatment.

Conclusion: The prior findings indicate that *Safoof-e-kalonji* are too much effective in Subclinical Hypothyroidism.

IndexTerms - Safoof-e-kalonji, Subclinical hypothyroidism, TSH

INTRODUCTION

Thyroid disorders are the most common endocrine conditions encountered in clinical practice. Persons of either sex and any age can be affected. The presentation of thyroid conditions can range from clinically obvious to clinically silent. In subclinical hypothyroidism, serum TSH levels are increased in clinically euthyroid patients with normal FT4 concentrations. Patients are usually asymptomatic or have minimal nonspecific symptoms that may be unrelated to hypothyroidism. The worldwide prevalence of subclinical hypothyroidism varies from 1 to 10%. The signs and symptoms of hypothyroidism includes fatigue, lethargy, cold intolerance, weight gain, constipation, dry skin, hoarseness, slowed mentation, and depressed mood, Classic physical signs of hypothyroidism include bradycardia, diastolic hypertension, and hypothermia; coarse, cool, and pale skin, loss of scalp hair's; hoarse, slow, and dysarthric speech, diffuse non pitting edema; and slowed deep tendon reflexes, particularly during the relaxation phase. However, none of these findings is sufficiently sensitive or specific for diagnosis.[9] There are no universally accepted recommendation for the management of subclinical hypothyroidism, but most recently published guidelines do not recommended routine treatment when TSH levels below 10mU/L.[1,4]

A certain medicinal plants are used in traditional medicine to treating many diseases. The medicinal plants uses in the thyroid disease are Piper longum (Pippali), Cartarva narvala (bark), Bauhiniia variegata (bark), Sida cardifolia (Leaves), Terminalia chebula (Fruits), Terminalia bellerica (Fruits), Glycyrrhiza glabra (roots), and Nigella sativa (Seeds).[3]

METHODS: THE INFORMED CONSENT WAS TAKEN FROM THE PATIENTS.

INTERVENTION: IN THIS CASE SERIES, PATIENTS WERE ADVISED TO TAKE *SAFOOF-E-KALONJI* (5GM) TWO TIMES DAILY ORALLY AFTER MEALS FOR A PERIOD OF 4 WEEKS.[5-8]

CASE I : A 30 YEAR OLD FEMALE PATIENT PRESENTED IN MOALEJAT OPD OF AKTCH, AMU WITH CHIEF COMPLAINTS OF UNEXPLAINED TIREDNESS, AND CHRONIC CONSTIPATION FROM LAST 6 MONTH .

THE HISTORY OF PATIENT WAS TAKEN PROPERLY THERE IS NO HISTORY OF DM &ANY OTHER CHRONIC ILLNESS. THE CBC WAS DONE(WNL),THYROID PROFILE WAS DONE IN WHICH T3 & T4 ARE WITH IN NORMAL LIMIT AND TSH LEVEL WAS 7.05.SHE WAS DIAGNOSED FOR SUBCLINICAL HYPOTHYROIDISM SUBSEQUENTLY SHE WAS ADVISED TO TAKE THE TEST FORMULATION OF *SAFOOF-E-KALONJI* IN THE DOSAGE OF 5 GRAM TWICE A DAY FOR A PERIOD 28 DAYS. SHE WAS SIGNIFICANTLY RELIEVED OF HER SYMPTOMS. AFTER 28 DAYS TSH LEVEL LABORATORY EVALUATED THAT WAS 4.51.

CASE II : A 35 YEAR OLD FEMALE PATIENT PRESENTED IN MOALEJAT OPD OF AKTCH, AMU WITH CHIEF COMPLAINTS OF HAIR FALL, TROUBLE IN CONCENTRATION AND IRREGULAR MENSES FROM LAST 3 MONTHS .

THE HISTORY OF PATIENT WAS TAKEN PROPERLY THERE IS NO HISTORY OF DM &ANY OTHER CHRONIC ILLNESS. PATIENT WAS CLINICALLY EXAMINED IN WHICH PALLOR WAS POSITIVE AND TENDERNESS IS PRESENT IN HYPOGASTRIC REGION. THE CBC WAS DONE(Hb- 9.5 GRAM%),THYROID PROFILE WAS DONE IN WHICH T3 & T4 ARE WITH IN NORMAL LIMIT AND TSH LEVEL WAS 5.15.SHE WAS DIAGNOSED FOR SUBCLINICAL HYPOTHYROIDISM SUBSEQUENTLY SHE WAS ADVISED TO TAKE THE TEST FORMULATION OF *SAFOOF-E-KALONJI* IN THE DOSAGE OF 5 GRAM TWICE A DAY FOR A PERIOD 28 DAYS. SHE WAS SIGNIFICANTLY RELIEVED OF HER SYMPTOMS. AFTER 28 DAYS TSH LEVEL LABORATORY EVALUATED THAT WAS 3.21.

CASE III : A 40 YEAR OLD FEMALE PATIENT PRESENTED IN MOALEJAT OPD OF AKTCH, AMU WITH CHIEF COMPLAINTS OF WEAKNESS & ACHES IN MUSCLES AND JOINTS, WEIGHT GAIN,HOARSNESS OF VOICE AND CHRONIC CONSTIPATION FROM LAST 5 YEARS .

THE HISTORY OF PATIENT WAS TAKEN PROPERLY THERE IS NO HISTORY OF DM &ANY OTHER CHRONIC ILLNESS. PATIENT WAS CLINICALLY EXAMINED IN WHICH XANTHELSAMA WAS FOUND. THE CBC WAS DONE(WNL),LIPID PROFILE WAS DONE WHICH WAS DERANGED. THYROID PROFILE WAS DONE IN WHICH T3 & T4 ARE WITH IN NORMAL LIMIT AND TSH LEVEL WAS 7.41.SHE WAS DIAGNOSED FOR SUBCLINICAL HYPOTHYROIDISM SUBSEQUENTLY SHE WAS ADVISED TO TAKE THE TEST FORMULATION OF *SAFOOF-E-KALONJI* IN THE DOSAGE OF 5 GRAM TWICE A DAY FOR A PERIOD 28 DAYS. SHE WAS SIGNIFICANTLY RELIEVED OF HER SYMPTOMS. AFTER 28 DAYS TSH LEVEL LABORATORY EVALUATED THAT WAS 4.31.

CASE IV : A 36 YEAR OLD FEMALE PATIENT PRESENTED IN MOALEJAT OPD OF AKTCH, AMU WITH CHIEF COMPLAINTS OF WEIGHT GAIN AND DEPRESSIVE ILLNESS FROM LAST ONE AND HALF YEARS .

THE HISTORY OF PATIENT WAS TAKEN PROPERLY THERE IS NO HISTORY OF DM &ANY OTHER CHRONIC ILLNESS. THE CBC WAS DONE(WNL),THYROID PROFILE WAS DONE IN WHICH T3 & T4 ARE WITH IN NORMAL LIMIT AND TSH LEVEL WAS 6.55.SHE WAS DIAGNOSED FOR SUBCLINICAL HYPOTHYROIDISM SUBSEQUENTLY SHE WAS ADVISED TO TAKE THE TEST FORMULATION OF *SAFOOF-E-KALONJI* IN THE DOSAGE OF 5 GRAM TWICE A DAY FOR A PERIOD 28 DAYS. SHE WAS SIGNIFICANTLY RELIEVED OF HER SYMPTOMS. AFTER 28 DAYS TSH LEVEL LABORATORY EVALUATED THAT WAS 4.12.

CASE V : A 32 YEAR OLD FEMALE PATIENT PRESENTED IN MOALEJAT OPD OF AKTCH, AMU WITH CHIEF COMPLAINTS OF ITCHY & DRY SKIN, FEELINGDOWN, HAIR LOSS AND WEIGHT GAIN FROM LAST 6 MONTHS.

THE HISTORY OF PATIENT WAS TAKEN PROPERLY THERE IS NO HISTORY OF DM &ANY OTHER CHRONIC ILLNESS. THE CBC WAS DONE(WNL),THYROID PROFILE WAS DONE IN WHICH T3 & T4 ARE WITH IN NORMAL LIMIT AND TSH LEVEL WAS 5.42.SHE WAS DIAGNOSED FOR SUBCLINICAL HYPOTHYROIDISM SUBSEQUENTLY SHE WAS ADVISED TO TAKE THE TEST FORMULATION OF *SAFOOF-E-KALONJI* IN THE DOSAGE OF 5 GRAM TWICE A DAY FOR A PERIOD 28 DAYS. SHE WAS SIGNIFICANTLY RELIEVED OF HER SYMPTOMS. AFTER 28 DAYS TSH LEVEL LABORATORY EVALUATED THAT WAS 2.25.

CASE VI : A 25 YEAR OLD FEMALE PATIENT PRESENTED IN MOALEJAT OPD OF AKTCH, AMU WITH CHIEF COMPLAINTS OF FEELING COLD FROM LAST 2-3 MONTHS.

THE HISTORY OF PATIENT WAS TAKEN PROPERLY THERE IS NO HISTORY OF DM &ANY OTHER CHRONIC ILLNESS. THE CBC WAS DONE(WNL),THYROID PROFILE WAS DONE IN WHICH T3 & T4 ARE WITH IN NORMAL LIMIT AND TSH LEVEL WAS 6.12.SHE WAS DIAGNOSED FOR SUBCLINICAL HYPOTHYROIDISM SUBSEQUENTLY SHE WAS ADVISED TO TAKE THE TEST FORMULATION OF *SAFOOF-E-KALONJI* IN THE DOSAGE OF 5 GRAM TWICE A DAY FOR A PERIOD 28 DAYS. SHE WAS SIGNIFICANTLY RELIEVED OF HER SYMPTOMS. AFTER 28 DAYS TSH LEVEL LABORATORY EVALUATED THAT WAS 2.01.

CASE VII : A 57 year old female patient presented in Moalejat OPD of AKTCH, AMU with chief complaints of mood liability and fatigue from 6-7 years. The history of patient was taken properly there is no history of DM & any other chronic illness. The CBC was done (WNL), Thyroid profile was done in which T3 & T4 are within normal limit and TSH level was 7.94. She was diagnosed for subclinical hypothyroidism subsequently she was advised to take the test formulation of *Safoof-e-kalonji* in the dosage of 5 gram twice a day for a period 28 days. She was significantly relieved of her symptoms. After 28 days TSH level laboratory evaluated that was 3.47.

CASE VIII : A 20 year old female patient presented in Moalejat OPD of AKTCH, AMU with chief complaints of weight gain, hair loss and body ache from last 1 years.

The history of patient was taken properly there is no history of DM & any other chronic illness. The CBC was done (Hb-11.0 gram%), Thyroid profile was done in which T3 & T4 are within normal limit and TSH level was 5.57. She was diagnosed for subclinical hypothyroidism subsequently she was advised to take the test formulation of *Safoof-e-kalonji* in the dosage of 5 gram twice a day for a period 28 days. She was significantly relieved of her symptoms. After 28 days TSH level laboratory evaluated that was 4.06.

CASE IX : A 46 year old female patient presented in Moalejat OPD of AKTCH, AMU with chief complaints of memory decline, puffy face and weight gain from last 2-3 years. The history of patient was taken properly there is no history of DM & any other chronic illness. The CBC was done (WNL), RFT was done which was within normal limit. Thyroid profile was done in which T3 & T4 are within normal limit and TSH level was 6.19. She was diagnosed for subclinical hypothyroidism subsequently she was advised to take the test formulation of *Safoof-e-kalonji* in the dosage of 5 gram twice a day for a period 28 days. She was significantly relieved of her symptoms. After 28 days TSH level laboratory evaluated that was 5.34.

CASE X : A 35 year old female patient presented in Moalejat OPD of AKTCH, AMU with chief complaints of extreme sleepiness, stomach bloating and from 10 months.

The history of patient was taken properly there is no history of DM & any other chronic illness. Patient was clinically examined there is no GIT related finding. The CBC was done (WNL), Thyroid profile was done in which T3 & T4 are within normal limit and TSH level was 5.31. She was diagnosed for subclinical hypothyroidism subsequently she was advised to take the test formulation of *Safoof-e-kalonji* in the dosage of 5 gram twice a day for a period 28 days. She was significantly relieved of his symptoms. After 28 days TSH level laboratory evaluated that was 3.76.

Table.1 Show the level of TSH Before and After treatment :

S.N	I	II	III	IV	V	VI	VII	VIII	IX	X
TSH Level Before treatment (mU/L)	7.05	5.51	7.41	6.55	5.42	6.12	7.94	5.57	6.19	5.31
TSH level After Treatment	4.51	3.21	4.31	4.12	2.25	2.01	3.47	4.06	5.34	3.76

Discussion: Hypothyroidism is a common disorder in which metabolic rate becomes decreased due to various causes but autoimmune disease (Hashimoto's thyroiditis) and thyroid failure following ¹³¹I or surgical treatment of thyrotoxicosis account for over 90% of cases except in areas where iodine deficiency is endemic. Women are affected six times more than men. The test drug Kalonji seeds (*Nigella Sativa*) in the form of fine powder having HarYabis temperament of 3rd grade that improves the symptoms of patient by enhancing the metabolic rate of body and also acts by Ilaj-bi-zzid that is integral part of principles of management in Unani system of medicine.

Conclusion: This study strongly suggests that the *Safoof-e-kalonji* is effective in the Management of subclinical hypothyroidism. This case series open a new vista in which *Safoof-e-kalonji* can be used in management of subclinical hypothyroidism therefore further study should be performed to establish the effectiveness of *safoof-e-kalonji* and also to evaluate the mechanism of action of this drug in management of subclinical hypothyroidism.

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