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A clinical comparative study & efficacy of polyherbal Unani formulations in subclinical hypothyroidism & overt hypothyroidism (Qillat-E-Ifraz-E-Ghudde Darqiyya)

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Abstract

The thyroid gland is a small organ that's located in front of the neck, wrapped around the windpipe (trachea). The thyroid secretes two essential hormones T₃ - Triiodothyronine & T₄ - Thyroxine, collectively called thyroid hormones. Their secretion is under the control of TSH from Pituitary and TRH from Hypothalamus. During infancy and childhood, adequate thyroid hormone is crucial for brain development. The prevalence of hypothyroidism in developed countries is around 4-5%, whereas it is about 11% in India. It is more common in women than in men. Hypothyroidism has multiple etiologies and manifestations. The most common clinical manifestations are weight gain, loss of hair, cold intolerance, lethargy, constipation, dry skin, and change in voice. The signs and symptoms of hypothyroidism differ with age, gender, severity of condition, and some other factors. The diagnosis is based on clinical history, physical examination and serum level of FT₃, FT₄, and TSH (Thyroid-stimulating hormone), imaging studies, procedures, and histological findings. The description of hypothyroidism as a disease is not directly found in Unani texts. However, the signs and symptoms of hypothyroidism resemble the clinical manifestation associated with Su-e-Mizaj Barid Maddi (derangement in cold temperament). These observations from Unani literature describe derangement in cold temperament and relate them to the clinical presentation of primary hypothyroidism in conventional medicine. Increasing dosage and continuous medicine make the patient drug dependent till the end of the life. Even after years of treatment, it is associated with failure to provide relief in clinical manifestations. Moreover, excessive thyroid hormone replacement carries the potential for serious long-term metabolic complications (e.g., accelerated osteoporosis). In the USM, the main emphasis of the principle of treatment (Usool-e-Ilaj) is to correct the abnormal constitution (Su-e-Mizaj) and alter the six prerequisites for existence (Asbab-e-Sitta Zarooriya) to restore normal health. It is a packaged treatment, that is, different components of treatment are given as a package form which includes correction in diet, different drugs, dosages form, and regimens. Due to certain limitation and associated side effects, this conventional medicine has certain limitations, which can be overcome by using unani herbal formulations either in single form or compound form. This unani medicine can limit the subclinical hypothyroidism at its level and prevent it from moving to overt hypothyroidism. The present Research study on "Efficacy of Unani Herbs in Treating Subclinical & Overt Hypothyroidism" was conducted on 10 patients from either gender whose TSH value was above normal (> 4.5ng/dl). They were divided in two groups of 5 patients each and was treated with separate group of medicine A & B. They were under observation for nearly 2 months. It was elicited that this disease effects the female most and of cold temperament. This research study ultimately concluded that Group A medicine has better response than Group B medicine with a 60% Cured, 20% Partial response & 20% No response. Group B also showed response but with efficacy lesser than Group A.

Keywords: Mizaj-Barid-Maddi, Usool-e-Ilaj, Su-e-Mizaj, Conventional medicine, Asbab -e-Sitta Zarooriya, Cold Temperment, Unani system of Medicine (USM), Phytoestrogens, Namkiyat

Introduction

It is a small butterfly shaped gland that sits at front of Throat. Thyroid lies below Adams apple, along the front of the windpipe. The thyroid has two side lobes, connected by a bridge (isthmus) in the middle.

When the thyroid is in its normal size, you can't feel it. Brownish-red in color, the thyroid is rich with blood vessels. Nerves important for voice quality also pass through the thyroid. The thyroid secretes two essential hormones T₃-Triiodothyronine & T₄-Thyroxine collectively called thyroid hormones. The main hormone is thyroxine, also called T₄. Thyroid hormones act throughout the body, influencing metabolism, growth and development, and body temperature. Their secretion is under the control of TSH from Pituitary and TRH from Hypothalamus. During infancy and childhood, adequate thyroid hormone is crucial for brain development.

Thyroid disease is a general term for a medical condition that keeps thyroid from making the right number of hormones. Thyroid typically makes hormones that keep the body functioning normally. When the thyroid makes too much thyroid hormone, body uses energy too quickly. This is called hyperthyroidism. Using energy too quickly will do more than make just tired-it can make heart beat faster, lose weight without trying and even make feel nervous. On the flip-side of this, thyroid can make too little thyroid hormone. This is called hypothyroidism. It can create tiredness, might gain weight and may even be unable to tolerate cold temperatures.

Concept of Hypothyroidism in Unani System of Medicine

The description of hypothyroidism as a disease is not directly found in Unani texts. However, the signs and symptom of hypothyroidism resemble the clinical manifestation associated with Su-e-Mizaj Barid Maddi (derangement in cold temperment), such as plethora (Imtila), excessive salivation (Kasrat-e-Luabe-e-Dahan), tiredness (Aa'yan), loss of appetite (Zoaf-e-Ishteha), excessive sleeping (Kasrat-e-Naum) and cold skin (Baroodat-e-Jildia). These signs and symptoms are the result of an excess abnormal phlegm (Ghair Tabayi Balgham) in the body.

Hypothyroidism (Qillat-e-Ifraz-e-Ghudude Darqiyya) is a condition where the thyroid gland is underactive and unable to produce enough thyroid hormone. These observations from Unani literature describe derangement in cold temperament and relate them to the clinical presentation of primary hypothyroidism in conventional medicine.

Epidemiology

Thyroid disease can affect anyone-men, women, infants, teenagers and the elderly. It can be present at birth (typically hypothyroidism) and it can develop as once age (often after menopause in women). A woman is about five to eight times more likely to be diagnosed with a thyroid condition than a man.

Risk of developing Thyroid disorder

One may be at a higher risk of developing a thyroid disease if:

- Have a family history of thyroid disease.
- Have a medical condition (these can include pernicious anemia, type 1 diabetes, primary adrenal insufficiency, lupus, rheumatoid arthritis, Sjögren's syndrome and Turner syndrome).
- Take a medication that's high in iodine (Amiodarone).
- Are older than 60, especially in women.

- Have had treatment for a past thyroid condition or cancer (thyroidectomy or radiation).

What is Hypothyroidism ???

It is an underactive condition in which thyroid gland does not produce enough of T₃ & T₄.

Types of Hypothyroidism		
1. Primary Hypothyroidism	2. Secondary Hypothyroidism	3. Tertiary Hypothyroidism

1. *Primary hypothyroidism* is due to the dysfunction of thyroid gland itself, though it is being stimulated properly by Hypothalamus & Pituitary.
2. *Secondary & Tertiary hypothyroidism* is said to be as Central Hypothyroidism as they occur due to the deficiency of TSH & TRH respectively.

Types of Primary Hypothyroidism

1. Subclinical Hypothyroidism
2. Overt Hypothyroidism

Etiology

Conditions that can cause hypothyroidism include:

- **Thyroiditis:** This condition is an inflammation (swelling) of the thyroid gland. Thyroiditis can lower the number of hormones that thyroid produces.
- **Hashimoto's thyroiditis:** A painless disease, Hashimoto's thyroiditis is an autoimmune condition where the body's cells attack and damage the thyroid. This is an inherited condition.
- **Postpartum thyroiditis:** This condition occurs in 5% to 9% of women after childbirth. It's usually a temporary condition.
- **Iodine deficiency:** Iodine is used by the thyroid to produce hormones. An iodine deficiency is an issue that affects several million people around the world..
- **A non-functioning thyroid gland:** Sometimes, the thyroid gland doesn't work correctly from birth. This affects about 1 in 4,000 newborns. If left untreated, the child could have both physical and mental issues in the future. All newborns are given a screening blood test in the hospital to check their thyroid function.

What is Subclinical Hypothyroidism??

It is a Biochemical change which otherwise means *low normal thyroid function*, means having a free Thyroxine (FT₄) within normal range and TSH level above normal level.

Subclinical Hypothyroidism	Overt Hypothyroidism
TSH > 4.50uIU/ml	TSH > 4.50uIU/ml
FT ₄ = 0.8-1.8ng/dl	FT ₄ < 0.8ng/dl
FT ₃ = 1.4-4.4pg/ml	FT ₃ < 1.4pg/ml

What causes Subclinical Hypothyroidism?

1. Autoimmune Thyroid Disease – Hashimoto's Thyroiditis
2. Partial Thyroidectomy during head and neck surgery
3. The use of radioactive iodine therapy, a treatment for Hyperthyroidism.
4. Taking medications that contain lithium, Amiodarone, Interferon Alfa, Tyrosine Kinase.....
5. Viral Thyroiditis

6. Congenital—due to iodine deficiency → Endemic Cretinism

How Subclinical Hypothyroidism Speaks??

1. Dry skin
2. Poor Memory
3. Slow thinking
4. Muscle weakness
5. Fatigue
6. Muscle cramps
7. Cold Intolerance
8. Puffy eyes
9. Constipation
10. Hoarseness of Voice
11. Hair loss
12. Slow growth & slow sexual development
13. Irregular MC

Subclinical Hypothyroidism & Its Impact over Adolescence

As the most prevalent cause of childhood and Adolescent Subclinical Hypothyroidism is Hashimoto's Thyroiditis, which is also termed as *Chronic Lymphocytic Thyroiditis* is characterised by Lymphocytic infiltration of thyroid gland, damage to thyroid follicular cells and impaired ability to produce thyroid hormones.

1. In adolescence, the most common manifestation is increase of the glandular volume.
2. *Delayed Puberty* or sometime *Pseudoprecocious puberty* is manifested as testicular enlargement in boys, breast development, and/or vaginal bleeding in girls but it lacks accelerated bone maturation and linear growth as seen in true puberty.
3. The female adolescent may experience an associated polycystic-ovaries
4. The possible association between pseudopuberty and hypothyroidism is the cross-reactivity between high TSH and FSH receptors.

Subclinical Hypothyroidism & Reproductive age

* It appears in 4-8% of reproductive age.

*Thyroid hormones are necessary for the proper functioning of reproductive system including ovaries, uterus & placenta.

* In the ovaries, thyroxine plays a role in the maturation of follicles (folliculogenesis), ovulation and of the Corpus Luteum.

Could subclinical hypothyroidism increases the risk of infertility??

If the women is sub clinically hypothyroid:

1. The ovaries may produce fewer mature follicles.
2. Prompt Ovulation is less often.
3. Delay maturation of Corpus luteum.
4. In affected women's, lower follicular count, lower Anti-Mullerian Hormone & reduce ovarian reserve is seen than in women with normal thyroid function.

Impact of subclinical hypothyroidism on pregnancy

The demand of thyroid hormones are more in *first trimester* than in second & third trimester as the fetus depends on mothers thyroid for its requirement. However, mothers thyroid need to be normal for normal fetal development.

Of particular Importance,

As — TSH level increases
FSH level increases
AMH level decreases
Thus – Follicular count & Ovarian reserve decreases

It is a telltale marker of Subclinical Hypothyroidism.

Thus, it concludes that Subclinical Hypothyroidism impacts right from Adolescence, Conception, Continuation of Pregnancy to Fetal Development.

Investigations

1. Blood Thyroid hormones – T₃, T₄ & TSH
2. Anti TPO antibodies
3. Ultrasound screening of Thyroid gland

Conventional management of hypothyroidism

* The treatment goals for hypothyroidism are to reverse clinical progression and correct metabolic derangements.

* Thyroid hormone is administered to supplement or replace endogenous production.

*Currently, the practical approach is routine levothyroxine therapy for persons with a persistent serum TSH of more than 10.0 mIU/L and individualized therapy for those with a TSH of less than 10.0 mIU/L.

Unani line of treatment (Usool-e-Ilaj)

As far as the management of hypothyroidism through Unani is concerned, hormonal replacement is not possible through drugs. However, one can interpret the pathogenesis of hypothyroidism in the context of Unani in which *derangement of cold temperament and excess of phlegm* is foremost and through its management, wholesome normal activity of the thyroid gland may be achieved.

Aims and Objectives

The aims and objectives of this study were as follows –

1. To prove the efficacy of unani treatment in the management of hypothyroidism.
2. To prove the efficacy of unani treatment in preventing the subclinical hypothyroidism from turning overt.
3. To provide a large population suffering from ulcerative colitis, a future possibility of safer treatment; this can be helpful in reducing the need of steroids and surgical processes.

Hypothyroidism & Sub clinical Hypothyroidism can be manage based on following Unani principles of Treatment.

- Ilaj bil Ghiza – Dietotherapy
- Ilaj bil Dawa – Pharmacotherapy
- Ilaj bil Tadbeer – Regimental therapy

1. Ilaj bil Ghiza – Dietotherapy

- While medication is necessary to manage healthy thyroid levels, there are also some lifestyle changes and things one can do to support healthy thyroid function — and to reduce some of the intensity of the symptoms.
- Nutrients play a big role in thyroid function. Role of Minerals (Namkiyat) can never be over seen in management of Hypothyroidism. A deficiency in iodine leads to thyroid issues and even its excess consumption can cause hypothyroidism.
- Minerals (Namkiyat) like Selenium (tuna, eggs, legumes) and zinc (oysters, chicken) support the

conversion of T4 hormone to the active T3 hormone, as well as all of the B-vitamins, which “can support energy and the body's stress response, must be included in diet.

- Vitamin D - support the immune system for those with an autoimmune thyroid condition, and support the production of many hormones in the body.
- Leafy greens, whole grains, nuts, seed, and zinc-rich legumes like peas, lentils, chickpeas, and beans - These foods contain amino acids like tyrosine, B-complex vitamins, minerals like selenium, and antioxidants — all of which support thyroid health.
- Spinach is a great source of many vitamins and minerals, including iron and some B-vitamins. Sweet potatoes are an excellent source of vitamin A, which supports thyroid hormone.
- Avoid some foods in Hypothyroidism like Soy. Soy is a big source of plant oestrogens also known as Phytoestrogens. Research shows that plant estrogens may inhibit the activity of enzymes that help in the production of thyroid hormones. Researchers also believe that soy may block iodine uptake and interfere with the absorption of thyroid medication. Soy foods include tofu, soy milk, and soy sauce.
- Goitrogens, which can inhibit the function of the thyroid gland, include cruciferous vegetables such as broccoli, Brussels, sprouts, cauliflower and fruits like peaches, pears, plums, raspberries, and strawberries.

2. Ilaj bil dawa-parmacotherapy of hypothyroidism

Unani preparations have a role in preventing subclinical Hypothyroidism from turning overt and also work in minimising subclinical conditions.

Materials and Methods

Selection of patients

A total of 10 patients from either sex, suffering from hypothyroidism or sub hypothyroidism were selected from patients, seen in Medical camps organised under the Organisation FUMO (Feminine Unani Medical Organisation), run under the society of *Medivision Institute of Medical Science Association*, bearing Registration number 149/2013, Hyderabad, Andhra Pradesh. Informed written consent in language suitable to the patients was obtained from all enrolled participants. These patients were divided in two groups i.e., Group A & Group B. Each group were allotted 5 patients from both the sexes above the age group of 10 and below the age group 40. The duration of study is 8 weeks with a weekly regular follow up. Patients were selected based on certain inclusion and exclusion criteria.

Inclusion criteria

Diagnosed cases of hypothyroidism on the basis of serum TSH, T3 and T4 levels.

- Patient's serum TSH level >4.5 μ IU/ml
 - Total serum T4 level less than or equal to normal value (total serum T4 = 4.5–12.5 μ g/dl)
 - Total serum T3 level less than or equal to normal value (total serum T3 = 80–220 ng/dl).
 - Patients having clinical features of hypothyroidism
1. Age 10 - 40 years
 2. Dry coarse skin
 3. Puffiness of the face and eyelids

4. Peripheral oedema
5. Constipation
6. Weakness
7. Breathlessness
8. Lethargy
9. Muscle ache
10. Menstrual abnormality
11. Hair loss

Exclusion criteria

1. Patients below the age group of 10 and above 40.
2. Patients with Pregnancy
3. Patients with congenital heart disease, uncontrolled hypertension, myocardial infarction, cardiac arrhythmias, and active malignant disease were excluded from the study.

Selected patients are under study in the following manner:

- History taking
- Physical examination
- Investigations

The drugs which are used in the treatment of Hypothyroidism are selected and grouped into following 2 groups:

Group 'A' – Habis (Astringent), Resolvent, Blood purifier,
Group 'B' – Anti-inflammatory, Aphrodisiac, Nervine tonic, Expectorant.

The drugs of Group A are:

1. Kachnal
2. Zanjabeel

This group consists of pills and Decoction.

Formula of Pill

Take green leaves of Barge Kachnal (*Bauhinia variegata*) and make pills in ginger juice (*Ginger-Zingiber officinalis*) – give one pill morning and evening before meals.

Formula of Decoction

1. Decoction of bark of kachnal to be taken 40-80ml before dinner, along with pills.
2. Ginger Juice – Grind 50gm Zanjabeel in 100ml of water, squeeze out the juice and give 10-20ml with 10ml Honey, morning before breakfast, along with pill.

Kachnal/Kachnar/Orchid tree

Synonyms: Butterfly ash, Camel foot tree, Hindi – Kachnar, Urdu – Kachnal, Telugu – Bodanta

Botanical Name: *Bauhinia variegata*

Temperment: Cold & Dry (2)

Products offered: Stem, bark, flowers, leaves & seeds.

Specific Action: Astringent (Habis), Intestinal tonic

Action: Hemostatic, astringent, sedative, analgesic, blood purifier and appetizer.

Uses: Bleeding gums, Hematuria, Menstrual disorder – anovulation And amenorrhoea, PCOD, Hypothyroidism, endometriosis, Fibroid, nasal polyp

Chemical constituents: Organic – Alkaloid, carbohydrate, tannins, steroids, phenols & glucosides. Inorganic – iron, calcium, potassium, magnesium.

Zanjabeel (Adrak) – Ginger**Synonyms:** Ginger, Zanjabeel, Adrak, sonth, allam.**Botanica name:** Zingiber officinale**Products used:** Rhizome**Temperment:** Hot 3 & Dry1**Chemical constituents:** Vegetable oil, Zingiberin, Resin, starch, Zingiberol, monoterpene.**Chief function:** Resolvent and Digestive**Functions:** Digestive, carminative, Brain tonic, Aphrodisiac, Nerve tonic, Anti-Helminthic, Laxative, Expectorant, Detergent.**Uses:** Fevers, Stomach diseases, sexual weakness, headache, leucorrhoea, menstrual pain heart diseases, Respiratory diseases.**The drugs of Group B are**1. **Mastagi romi**2. **Zafran****Preparation:** Mastagi romi 1gm and Zafran 2mg to be given in powdered form, morning n evening before meals.**Mastagi****Synonyms:** Mastagi roomi, Mastic gum**Botanical Name:** Pistacia lentiscus**Temperment:** Hot & Dry (2)**Products used:** Gum, Resin**Chief function:** Diuretic**Functions:** Laxative, carminative, liver tonic, expectorant, absorbent, anti-inflammatory, astringent.**Uses:** Constipation, weakness of Digestive system, haemorrhages, cold & catarrh, Bronchitis, Asthma, Eczema, Scabies and other skin eruptions.**Zafran (Saffron)****Synonyms:** Zafran, saffron.**Scientific name:** Crocus sativus L**Products used:** Dried stigmas**Temperment:** Warm & Dry**Chief function:** works in Infertility**Functions:** Expectorant, Aphrodisiac, sedative, carminative, nervine tonic, digestive, moisturiser, analgesic.**Uses:** Asthma, cough, whooping cough (pertusis), insomnia, cancer, atherosclerosis, flatulence, depression, Alzheimer's disease, haemoptysis, heart burn, dry skin, menstrual cramps, premenstrual syndrome, premature ejaculation, infertility, alopecia.**Table 1:** Incidence of Hypothyroidism (Qillat-e-Ifraz-e-Ghudude Darqiyya) According to Sex

Sex	Total Cases	Percentage
Females	07	70%
Males	03	30%
Total	10	100%

In this research study on Hypothyroidism, the incidence is more in females with 70% than males i.e., 30%.

Table 2: Incidence of Hypothyroidism (Qillat-e-Ifraz-e-Ghudude Darqiyya) According to Mizaj

Temperment (Mizaj)	Female Number	Female Percentage	Male Number	Male Percentage
Safravi	00	00%	00	00%
Damavi	02	20%	01	10%
Balghami	05	50%	02	20%
Saudavi	00	00%	00	00%
Total	07	100%	03	100%

The above-mentioned table shows that Balghami mizaj people suffer more from Hypothyroidism in either sex. As per unani literature, sign and symptoms of hypothyroidism is attributed to derangements in cold temperment (Su-e-Mizaj Barid Maddi) and excess of phlegm accumulation.

Table 3: Incidence of Hypothyroidism (Qillat-e-Ifraz-e-Ghudude Darqiyya) According to Investigation

Thyroid Profile	No. Of Cases	Percentage
TSH (> 4.50uIU/ml)	10	100%
TSH (< 4.50uIU/ml)	00	00%
FT ₃ (< 1.4ng/dl)	00	00%
FT ₄ (< 0.8ng/dl)	03	30%
Total	10	100%

Raised TSH above normal was taken as prime tool in investigations to establish the Diagnosis of Hypothyroidism & Subthyroidism which was raised in all the cases of both the groups with normal Free T3 but Free T4 was below normal in 30% cases.

Normal range of thyroid profile

TSH = /< 4.50uIU/ml

FT₄ = 0.8-1.8ng/dlFT₃ = 1.4-4.4pg/ml**Table 4:** Incidence of Hypothyroidism (Qillat-e-Ifraz-e-Ghudude Darqiyya) According to Therapeutic Response in Gr.A Patient

Response	No. Of Patients	Percentage
Cured	03	60%
Partial Response	01	20%
No Response	01	20%
Total	05	100%

The therapeutic efficacy of Group A medicine was evaluated as cured 60%, partial response 20% & No response 20%.

Table 5: Incidence of Hypothyroidism (Qillat-e-Ifraz-e-Ghudude Darqiyya) According to Therapeutic Response in Gr.B Patient

Response	No. Of Patients	Percentage
Cured	02	40%
Partial Response	02	40%
No Response	01	20%
Total	05	100%

The therapeutic efficacy of Group B medicine was evaluated as cured 40%, partial response 40% and no response 20%.

Table 6: Comparative Study of Management between Group A and Group B Medicine

Response	Group A		Group B	
	No. Of Cases	Percentage	No. Of Cases	Percentage
Cured	03	60	02	40
Partial Response	01	20	02	40
No Response	01	20	01	20
Total	05	100	05	100

The above table shows the comparative study of efficacy between Group A & Group B Medicine with a effective response of 60% seen with Group A medicine.

Unani Pharmacopoeial Formulation Used in Management of Hypothyroidism

1. Itrifale Ghududi
2. Tiryaaqe Arba
3. Jawarische Mastagi banusqa kalan
4. Jawarische Zanjabeel
5. Habbul Ghaar
6. Dawaul kurkum kabeer
7. Jawarische Bisbasa
8. Sufoof-e-kachnal
9. Jawarische Jalinoos

Discussion and Conclusion

Subclinical hypothyroidism occurs in the clinical setting of a serum TSH level above the upper limit of normal despite a normal serum free thyroxine concentration. Initiating levothyroxine replacement therapy is recommended for all patients with a TSH greater than 10 uIU/ml, even if the free thyroxine concentration is within normal laboratory range. Due to lifelong consumption and associated side effects, this conventional medicine has certain limitations, which can be overcome by using unani herbal formulations either in single form or compound form as mentioned in this research paper. This unani medicine can limit the subclinical hypothyroidism at its level and prevent it from moving to overt hypothyroidism. Simultaneous use of unani herbs along with Levothyroxine can lower the intake dosage of levothyroxine. Use of unani medicine can even improve the secondary sexual characters in either sex which generally get diminished in hypothyroid patients. Certain unani formulations can be given safely in pregnant women suffering from hypothyroidism.

The present Research study on "A Clinical Comparative Study & Efficacy of Polyherbal Unani Formulations In Subclinical Hypothyroidism & Overt Hypothyroidism" was conducted on 10 patients from either gender whose TSH value was above normal (> 4.50uIU/ml). They were divided in two groups of 5 patients each and was treated with separate group of medicine A & B. They were under observation for nearly 2 months. It was elicited that this disease affects the female most and of cold temperament. This research study ultimately concluded that Group A medicine has better response over Group B medicine with a 60% Cured, 20% Partial response & 20% No response. Group B also showed response but with efficacy lesser than Group A.

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