

To Evaluate the Safety and Efficacy of a Unani Formulation in Iktisabi Qillat-E-Ifrac-E-Darqia (Autoimmune Hypothyroidism) – A Pilot Clinical Study (A Short Research Communication)

*¹Naquibul Islam, ²Kauncer and ³Basharat Bukhari

¹Research Officer (Unani) & Professor, PG Department of Moalajat, Regional Research Institute of Unani Medicine, Srinagar, Jammu and Kashmir

²Junior Research Fellow (Unani), Regional Research Institute of Unani Medicine, Srinagar, Jammu and Kashmir

³Technical Officer (Unani), Regional Research Institute of Unani Medicine, Srinagar, Jammu and Kashmir

Abstract

The purpose of the study was to evaluate the safety and efficacy of new Unani formulation in *Iktisabi qillat-e-frac-e-darqia* (autoimmune hypothyroidism) on five patients. For this purpose, decoction of semi-crushed powder made of six Unani herbal drugs was given twice daily in the morning and in the evening to the patients as per the method described in this paper for a duration of 90 days. The study was conducted in the year 2010-2011. The study period was one year. The patients were advised to take sour foods and fruits. After completion of the study, the therapy showed a significant improvement in the patients ($p=0.07$). The formulation had no any side effects and the patients felt overall sense of wellbeing and lighter. Details have been presented in this paper.

Keywords: Safety, Efficacy, Unani Formulation, Hypothyroidism

Hypothyroidism

This is known as *Qillat-e-frac-e-Darqia* in Unani System of Medicine or hypothyroidism in Modern Medicine. It is a condition in which body lacks sufficient thyroid hormone (Norman; *et al.* 2011, Mathur, *et al.* 2011, Romshoo, *et al.* 2009). Its other alternate names are autoimmune thyroiditis and Hashimoto's thyroiditis. The main purpose of thyroid hormone is to run the body's metabolism in order and the lack of sufficient thyroid hormone will affect metabolism (Norman *et al.*; 2011). There are two common causes of hypothyroidism, the first which results due to inflammation of the thyroid gland, thus becoming incapable of producing sufficient hormone; and the second major cause is the broad category of medical treatments such as surgical removal of a portion or all of the thyroid gland. The thyroid gland uses iodine from foods such as seafood, bread and salt to produce thyroid hormones. The two most important thyroid hormones are thyroxine (T_4) and tri-iodothyronine (T_3), which account for 99% and 1% of thyroid hormones present in the blood respectively. If any disruption occurs at any of these levels, a defect in thyroid hormone production may result in a deficiency of thyroid hormone called as hypothyroidism (Mathur *et al.* 2011).

The earliest reference in regard to Iodine use was found in Greek literature. The ancient Greeks, including *Galen*, used the marine sponge to treat swollen glands. The Swiss physician, Coindet, in 1813, hypothesized that the traditional treatment of goiter with seaweed was effective because of its iodine content and successfully treated goitrous patients with iodine. The French chemist Chatin in 1851 hypothesized that iodine deficiency was the cause of goiter (Zimmermann, *et.al.*; 2008). In Greek Medicine, both sea and rock salt were well known to the ancient Greeks and the healing methods of *Buqarat* (Hippocrates, 460 BC)

* Author for Correspondence: naquibislam@gmail.com

especially made frequent use of salt. *Ibn Sina's* (Avicenna 980-1037 A.D.) recipes also used salt. He emphasized the presence of Iodine and iron in coastal sea salt (Anonymous 2011). As such, there is neither the exact description of this disease nor any direct reference for the treatment is available in *Unani* System of Medicine but the descriptions with more or less similar signs and symptoms are found in the literature of Greek Physicians (Zimmermann, 2008; et al; Anonymous 2011) which nearly coincide with this disease.

A study was conducted on Hypothyroidism with intervention of a compound *Unani* formulation namely; *Akseer Darqeen* at Aligarh (Anees, 2002) but it was a preliminary one. An epidemiological study was also conducted in southern Kashmir in India on 886 patients from 2004-2009 including 724 (81.72%) females and 162 (18.28%) males in the age group of 12-75 years and it was found that the prevalence of primary hypothyroidism (especially subclinical hypothyroidism) is very high in Kashmiri population. It included 856 patients (96.61%) of primary hypothyroidism and 30 patients (3.86%) had subclinical hypothyroidism (TSH<10 μ IU/ml). Primary hypothyroidism is the most common cause of elevated TSH (Romshoo, *et al.* 2009). The symptoms of hypothyroidism include fatigue, weakness, weight gain or increased difficulty in losing weight, coarse, dry hair, dry, rough pale skin, hair loss, cold intolerance, muscle cramps and frequent muscle aches, constipation, depression, irritability, memory loss, abnormal menstrual cycles and decreased libido. Hypothyroidism can often be diagnosed with a simple blood test such as Thyroid profile (Hasan *et al.*, 2006).

The patients of thyroid diseases, mainly hypothyroidism, have been attending to the OPDs of Regional Research Institute of Unani Medicine, Srinagar, for *Unani* treatment. The number is on an increasing trend and 98% is primary hypothyroidism which includes subclinical hypothyroidism up to 98% and rest 2% includes both mild hypothyroidism and overt hypothyroidism in which about 85 to 95% is female and rest male. On an average, 4-6 patients of primary hypothyroidism were reported at three OPDs of this institute which worked out to be about 2.5 to 3% patients of hypothyroidism. This observation coincides with a study conducted in southern Kashmir in 2004-2009. The management of hypothyroidism involves Thyroxin Replacement Therapy (TRT), starting from low dose of 50 micro grams daily for three weeks, then increase, thereafter to 100 micro grams daily for three weeks and finally, to a maintenance dose of 100-150 micro grams daily in single dose since its half-life is 07 days. Then repeat Thyroxin Function Test(TFT) was done after six weeks to maintain the dose usually in increments of 25 micro grams daily.

In view of increasing number of patients of hypothyroidism in Kashmir and failure of a number of the present conventional treatment, this study 'To Evaluate the Safety and Efficacy of a *Unani* Formulation in *Iktisabi Qillat-e-Ifraz-e-Darqia*

(Autoimmune Hypothyroidism) – A Pilot Clinical Study’ was conducted on five patients during 2010-2011 at Regional Research Institute of Unani Medicine, Srinagar, Jammu and Kashmir, India.

Objective

To evaluate the safety of *unani* Formulation in *iktisabi qillat-e-ifraz-e-darqia* (autoimmune Hypothyroidism)

Material and Methods

Five female patients of diagnosed case of autoimmune (primary) hypothyroidism were included in the study, two belonged to the age range of 20-30 years, two 30-40 years and one 40-50 years. Their age ranged from 24 to 45 years with mean age of 33.6 years. Child-bearing women, pregnant and breast-feeding women were not included in the study. Though the patients were already screened and diagnosed by the Allopathic Doctors but Thyroid Profile was done before starting the treatment. After that, this formulation was given to the patients. The follow-ups were made on every 30th day. The last follow-ups were made on 90th day and post therapeutic Thyroid Profile in each patient was done on 91st day. The duration of therapy was 90 days and the duration of the study was one year. The patients were advised to take sour foods and fruits.

Two patients who had stopped Allopathic treatment for hypothyroidism two months ago and three patients who had detected it in the blood but had not taken any treatment were included in this study. Although, Thyroid Profile was done before and after the therapy for each patient, but for the sake of lucid presentation and explanation of response of therapy, only TSH level in each patient was taken into consideration.

The decoction of the following six *Unani* herbs in the form of semi-crushed powder of 30 gm, purchased from the local market, was given to the patients as per the method given below:

• <i>Aloo Bukhara (Prunus domestica)</i>	5 gm
• <i>Beikh Badyan (root of Foeniculum vulgare Mill)</i>	5 gm
• <i>Beikh Kasni (root of Cychorium intybus Linn)</i>	5 gm
• <i>Tamarhindi (Tamarindus indica)</i>	5 gm
• <i>Ustukhuddus (Levendula stoechs Linn)</i>	5 gm
• <i>Zeera Safaid (cuminum cyminum Linn)</i>	5 gm

Method of Preparation of Decoction and its Mode of Administration

The decoction made of semi-crushed powder of 6 simple Unani herbs(Unani Formulation), 05 gm each, total of 30 gm was prepared in 05 times of water,(i.e.,

150 ml of water), boiled for 05 minutes, filtered with ordinary filter paper and the decoction so prepared was given twice daily in the morning before breakfast. Decoction was again prepared (repeated) after boiling it for five minutes in the evening from the residue left in the morning in 150 ml of water and given after evening tea. The patients were asked to report for follow-up on every 30th day.

Results

After completion of the therapy, (90 days) it was found that the total TSH value of five patients was 227.39 μ IU/mL on day 0 which came down to as low as 25.75 μ IU/mL on 91st day. There was a reduction of 201.64 μ IU/mL in five patients on 91st day. Similarly, the mean TSH value of the five patients on day 0 was 45.47 μ IU/mL which came down to as low as 05.15 μ IU/mL on 91st day. There was a mean reduction of TSH value of 40.32 μ IU/mL in five patients after completion of the therapy (Table 1). A significant therapeutic response was seen Figure 1 ($p=0.07$).

Discussion

Since it was hypothesized that this disease is of yellow bilious-black bilious in origin, the first five Unani drugs, which are meant for the diseases due to yellow bilious-black bilious humors, were chosen in order to correct the imbalance of humors in the body which might have caused this disorder and the last(sixth) drug having diuretic action (Ali, 1979) was included in order to induce diuresis to get body detoxified from ill effect/s of the disease through complex phenomenon under the influence of decoction. It seems that, these drugs had tried to maintain a balance of humors thus enabling a significant reduction of TSH levels in all five patients. After the treatment, the patients felt overall a sense of wellbeing and lighter. The therapy had no any side effects.

Table1: Pre and Post Treatment TSH Values of Five Patients of Hypothyroid.

S. No (patients)	Value of TSH on day 0 (μ IU/m L)	Value of TSH on day 91 (μ IU/m L)	Reduction in TSH after day 91 (μ IU/m L)
1.	65.92	10.75	55.17
2.	20.57	3.21	17.36
3.	112.34	0.01	112.33
4.	8.47	3.84	4.63
5.	20.09	7.94	12.15
Total	227.39	25.75	201.64
Mean	45.47	05.15	40.32

Conclusion

It is, therefore, concluded that this new Unani formulation may be tried in cases of autoimmune hypothyroidism as an alternate.

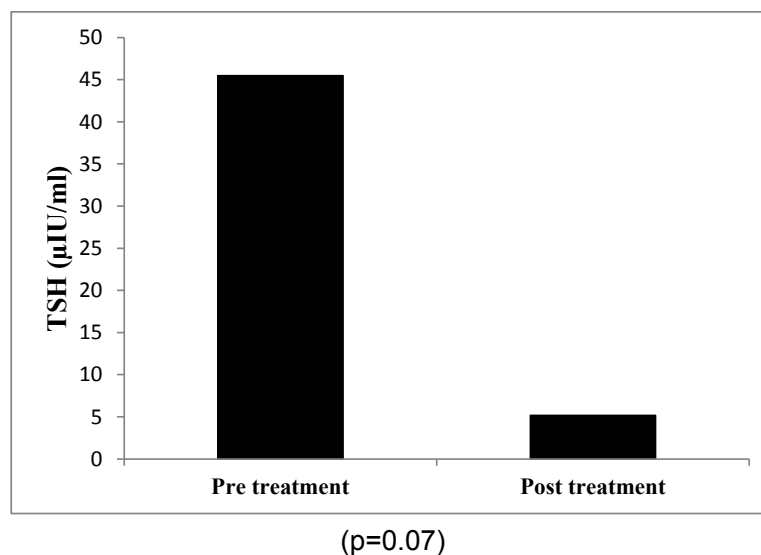


Fig. 1: Chart Presentation of Pre and Post Treatment Response of Unani Formulation in 05 patients of Autoimmune Hypothyroid:

Note:

1. The Chart presentation ($p=0.07$) also shows a significant therapeutic response
2. Data shown are the mean ($n=5$)

Acknowledgement

The authors are thankful to CCRUM, New Delhi, for giving permission to carry out this pilot study at Regional Research Institute of Unani Medicine, Srinagar, Jammu and Kashmir, India. Thanks are also due to the patients for their active participation and co-operation in completing this study.

References

1. Ahmad, Iftikhar., Ali, Hasan., Sarwar, Muhammad. and Ali, Khursheed Hasan. (2006) Assessment of Hypothyroidism in Diffuse Non-scarring Alopecia. *J Pak Assoc Derma.* 16(1):220-23.
2. Anees, Arif (2002) Qillat-e-Afraz-e-Darqiya Ka Tahiqeeqee Motaala Aur Uske Elaj Mein Akseer, Darqeen Ki Afadiyat Ka Jaiza. MD Thesis, Department of Moalajat, Faculty of Unani, Medicine, AMU, Aligarh, India.

3. Ali, Syed Saifuddin (1979) Unani Advia Mufrida.No.1. NCPUL, New Delhi, pp.15, 23-33.
4. Anonymous (2011) Educating instead of medicating, polish cows and war on cancer, Issue 19. ([http://www.curezone.com/forums/fm.asp?i=67182.](http://www.curezone.com/forums/fm.asp?i=67182))
5. Norman, James (2011) Hypothyroidism : overview, causes and symptoms (<http://www.endocrineweb.com>)
6. Mathur, Ruchi. and Shiel, Jr. William C. (2011) Hypothyroidism. (<http://www.medicinenet.com/hypothyroidism/article.htm>).
7. Romshoo, Ghulam Jeelani (2009) Clinical profile of hypothyroid patients of south Kashmir. *JAPI*, Vol-57.
8. Zimmermann, Michael B (2008) Research on iodine deficiency and goiter in the 19th and early 20th centuries, American Society for Nutrition. *J. Nutr.* 138:2060-2063.

(Note: This research article was presented by the Corresponding Author at the 'National Seminar on the Role of Unani Medicine in Non-Communicable Diseases' held at CCRUM, New Delhi, during 14-15 January 2015.)

सारांश

इक्तिसाबी किल्लत-ए-इफराज-ए-दरक्विया (ऑटोइम्यून हाइपोथायराडिज़्म) में यूनानी औषधियों की प्रभावकारिता एवं सुरक्षा का मूल्यांकन करना - एक पायलट नैदानिक अध्ययन (एक संक्षिप्त अनुसंधानिक संचार)

¹नकिबुल इस्लाम ²कौसर और ³बशारत बुखारी

अध्ययन का मुख्य उद्देश्य पाँच रोगियों पर इक्तिसाबी किल्लत-ए-इफराज-ए-दरक्विया (ऑटोइम्यून हाइपोथायराडिज़्म) में यूनानी मिश्रणों की सुरक्षा और प्रभावकारिता का मूल्यांकन करना था। इस उद्देश्य के लिए, छः यूनानी हर्बल औषधियों से बना आधा पीसा हुआ जोशांदा (पेपर में वर्णित विधि के अनुसार) नब्बे दिनों की अवधि के लिए रोगियों को प्रतिदिन दो बार सुबह और शाम दिया जाता है। वर्ष 2010-2011 में यह अध्ययन किया गया। अध्ययन की समय अवधि एक वर्ष की थी। रोगियों को खट्टा भोजन एवं फल खाने की सलाह दी गई। अध्ययन के पूर्ण होने के उपरान्त, रोगोपचार से रोगियों (पी=0.07) में एक महत्वपूर्ण सुधार देखा गया। इन मिश्रणों का कोई भी दुष्प्रभाव नहीं था और रोगियों ने हल्का और सुखी महसूस किया। विवरण पेपर में प्रस्तुत किया है।

