Reasons for the prescription of natural remedies in the treatment of autoimmune thyroiditis with different degrees of hypothyroidism

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Abstract. Background. Autoimmune thyroiditis is the most common cause of hypothyroidism. If the therapy of overt hypothyroidism by prescribing hormone replacement therapy is quite clear, then the problem of treating the patients with subclinical hypothyroidism remains open. The purpose of this study was to determine the effectiveness of using the combined natural drug Thyreos in the treatment of autoimmune thyroiditis without thyroid dysfunction, at the stage of subclinical hypothyroidism as monotherapy and in the comprehensive therapy of overt hypothyroidism in the combination with L-thyroxine. Materials and methods. Forty-nine patients aged 48.26 ± 13.52 years with autoimmune thyroiditis were examined. All individuals were divided into 3 groups. Group 1 included 20 patients with autoimmune thyroiditis without thyroid dysfunction, group 2 consisted of 16 people with newly diagnosed subclinical hypothyroidism, and group 3 included 13 patients, who previously received L-thyroxine therapy for overt hypothyroidism. All patients were prescribed Thyreos 1 capsule twice a day for a period of 3 months as monotherapy (groups 1 and 2) or in addition to hormone replacement therapy (group 3).

Results. When evaluating complaints, it was found that after 3 months of taking the drug, weakness and rapid fatigue were observed in a significantly smaller number of patients in all three groups (p < 0.05). Complaints of dryness and hair loss in individuals of the first two groups (p < 0.05) were also probably less frequent after 3 months of therapy with Thyreos. As a result of treatment, dry skin was significantly reduced in patients of only the first examined group (p = 0.024). In people with newly diagnosed subclinical hypothyroidism, a significant dynamics of thyroid-stimulating hormone level was determined. In patients with overt hypothyroidism, the supplementation of Thyreos to L-thyroxine significantly reduced thyroid-stimulating hormone content and increased free thyroxine level without changing the dose of hormone replacement therapy. All examined individuals tolerated the drug well, without any adverse reactions. Conclusions. In the presence of subclinical and overt hypothyroidism on the background of autoimmune thyroiditis, the use of a combined natural remedy Thyreos is quite justified. The drug showed a clinically significant positive effect, which manifested itself in the improvement of well-being and hormonal status parameters of patients, both as monotherapy in subclinical hypothyroidism and in combination with L-thyroxine — in overt one. Preliminary results of Thyreos effect on the suppression of the autoimmune process in the thyroid gland need further clarification with the involvement

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Introduction
Autoimmune thyroiditis (AIT) is currently one of the most common endocrine diseases in Ukraine and around the world. As a result of autoimmune aggression against thyroid tissue it is developed diffuse compaction of the organ, its lymphocytic infiltration due to the high titers of antithyroid antibodies. This leads to the destruction of thyroid follicular cells and, as a result of the death of structural and functional units, hypothyroidism. The potential development of hypothyroidism on the background of autoimmune aggression determines the importance of early detection of AIT and carrying out some measures to prevent thyroid dysfunction.

AIT is a polyetiologic disease. Both genetic and environmental factors play a role in its development. AIT without dysfunction of the gland has no clinical significance. Only at the stage when its chronic course leads to abnormalities in the thyroid gland function and the development of hypothyroidism, patients need careful medical attention in order to timely prescribe adequate therapy to minimize the pathological impact of thyroid deficiency on the functioning of almost all organs and systems. AIT is the most common cause of thyroid hypofunction, occurring in approximately 5% of the adult population [1] and affects, first of all, the central nervous and cardiovascular systems, musculoskeletal system, gastrointestinal tract, reproductive axis, and in childhood — disrupts psycho-somatic development.

The main difficulties in the diagnosis of hypothyroid goiter are the nonspecificity of symptoms and their high prevalence in other somatic and mental diseases. It is necessary to pay attention to the presence of the so-called syndrome of non-endocrine pathology. For example, a decrease in total triiodothyronine (T3) may occur in coronary heart disease and angina; decrease in total thyroxine (T4) occurs in resuscitation patients and patients who are constantly receiving glucocorticoid therapy; increased T4 may be accompanied by cirrhosis of the liver, viral hepatitis and mental disorders. Meanwhile, simultaneous laboratory determination of free T4 (Tf), free T3 (Tf) and thyroid-stimulating hormone (TSH) allows for differential diagnosis of non-endocrine pathology and thyroid dysfunction.

Subclinical hypothyroidism is a condition that can be diagnosed only in the laboratory — with an increase in TSH levels from 4.0 to 10 mIU/l in combination with normal levels of thyroid hormones and the absence of any clinical manifestations of hypothyroidism. Such patients may have some complaints, but they are not specific to hypothyroidism and do not allow a preliminary diagnosis based solely on the clinical picture.

Management of patients with overt hypothyroidism is quite unambiguous and includes the use of levothyroxine drugs as a replacement therapy. At the same time, the feature of the treatment of subclinical hypothyroidism is the individual approach to the appointment of replacement therapy. The latter is used in case of an increase TSH level in the dynamics of observation on the background of high titers of antithyroid antibodies. It should also be noted that hormone replacement therapy of subclinical hypothyroidism in elderly patients (61–80 years) may be dangerous due to the development of side effects at the presence of comorbid pathology. The heartbeat, tachycardia, arrhythmia, angina are among these effects. In addition, according to the drug instruction, L-thyroxine is contraindicated in patients with acute myocardial infarction, although the presence of concomitant hypothyroidism complicates the course of vascular catastrophes and adversely affects the effectiveness of emergency therapy.

According to the European Thyroid Association (ETA), the treatment of patients with subclinical hypothyroidism still remains a debatable issue [2]. On the one hand, hypothyroidism requires hormone replacement therapy. There is even a clinical case of hypothyroid coma developed in a patient with subclinical hypothyroidism [3]. On the other hand, there are multiple evidences that the management of subclinical hypothyroidism differs from the overt one, and the need for L-thyroxine at a TSH level of less than 10 mIU/ml is at the discretion of the endocrinologist. Thus, A. Grossman and co-authors, based on the observation of nearly 2,000 patients with subclinical hypothyroidism, claim that L-thyroxine treatment is associated with a significantly increased risk of death in patients over 65 years of age [4]. Supporting this view, G.E. Bekkering and co-authors after careful analysis of the advantages and disadvantages of hormone replacement therapy prescribing for subclinical hypothyroidism during 1.5 years of follow-up, concluded that such patients are not indicated for L-thyroxine [5].

All the above reasons the search for alternative drugs that could be used in situations where it is impossible to prescribe L-thyroxine therapy as well as in cases of subclinical hypothyroidism, when there are no absolute indications for hormone replacement therapy. Simultaneously there is a question of prevention of deterioration and the transition of subclinical hypothyroidism to overt one.

During the existence of humankind medicinal plants, the components of which have a positive effect on the functioning of many organs and systems were invented and are still used. They are distinguished from synthetic drugs by the almost complete absence of side effects and contraindications for use. Some herbs and spices that people eat also have good health benefits.

In recent years, physicians have become much more interested in medicinal plants, especially those used in traditional Indian medical systems, including Ayurveda, Yoga, Naturopathy, Yunani, Siddha, Homeopathy, Sowa Rigpa, in relation to their centuries-old history and worldwide recognition [6]. It is believed that drugs derived from plants are much safer and show great effectiveness in the treatment of various diseases. Folk medicinal traditions play a significant role in the interaction of man and the environment.

The prevalence of thyroid dysfunction is growing worldwide at an alarming rate. In India for many centuries in the treatment of goiter people are widely used herbal medicines [7]. Among them, a worthy place was occupied by Thyreos — a combination of plant and natural components [8].

The main component of Thyreos is Bacopa Monneri (250 mg in one capsule), which contains alkaloids, flavonoids, bacosides, saponins, apigenin, querctin, sterols. In
It influences on the synthesis of thyroid hormones indirectly and has a hypolipidemic effect, especially important in patients with hypothyroidism with concomitant diabetes of the cardiovascular system.

Piperine itself has a hypolipidemic effect, especially important in patients with hypothyroidism with concomitant diabetes of the cardiovascular system.

The second dose component of the drug Thyreos is Guggul (Commiphora mukul) (200 mg in one capsule). Experimental studies in mice [9] also proved the stimulating effect of guggulsterone — the active ingredient of the resin produced by the plant stem — on thyroid function. In addition, this component has a local anti-inflammatory effect, antioxidant, hypolipidemic activity and enhances the transformation of T4 to T3 in the liver, thereby increasing the concentration of active hormones in the serum and, through the feedback mechanism, reducing TSH levels [11]. That is, it helps to compensate for hypothyroidism. It should be noted that the components of the drug, in addition to self properties, potentiate the effect of each other.

Potentilla alba (also known as foxglove, five-leaf clover) is a unique plant used to treat a variety of diseases. One capsule of Thyreos contains 50 mg of potentilla, which contains elementary iodine, iodide acid anion, micro- and macroelements (Mn, Cu, Zn, Se, Co, Fe, Si, etc.). It is unique that this plant can be used to compensate for metabolism in hypo- and hyperthyroidism both. This is possible due to the biologically active compound of albinin, which is located in the underground part of the plant and exhibits thyroid-stimulating activity [12].

The effect of Coleus (Coleus forskohlii), 30 mg in a capsule of Thyreos, is mediated by its derivative forskolin, which is able to activate directly (bypassing the receptors) adenylyl cyclase and increase the level of cyclic adenosine monophosphate (cAMP) in the cell. cAMP is an important secondary mediator in the intracellular signaling cascades, which provide the action of many hormones and neurotransmitters, as well as is necessary for intercellular interaction in the hypothalamic — pituitary — thyroid axis to provide negative feedback. Thus, forskolin from coleus improves thyroid function by mimicking the action of TSH by increasing cAMP levels.

It is well known that the essential amino acids tyrosine and iodine are necessary for the synthesis of thyroid hormones. One capsule of Thyreos contains 70 mg of L-form of tyrosine — L-tyrosine — and a source of iodine — Laminaria sugary (20 mg). These two components of Thyreos are directly involved in the synthesis of thyroxine and triiodothyronine.

Piper (Piper longum) and marich (Piper nigrum), 10 mg in each capsule of Thyreos, have their effect due to the alkaloid piperine. Owing to the inhibition of detoxification enzymes that break down drugs (eg, CYP3A4), and increased intestinal absorption of drugs piperine increases the bioavailability of other components of Thyreos. In addition, piperine itself has a hypolipidemic effect, especially important in patients with hypothyroidism with concomitant diabetes of the cardiovascular system.

Selenium plays a special role in the thyroid gland activity. It influences on the synthesis of thyroid hormones indirectly through selenoproteins [13–17]. Selenium-containing deiodinases, which convert the inactive form of thyroid hormones (T3) to the active one (T4) by removing one iodine atom from the outer ring, mainly affect thyroid status [18]. But this does not limit the role of selenium in the thyroid gland. Thus, the selenoprotein glutathione peroxidase protects the thyroid gland from oxidative stress [19]. 50 mcg of selenium is included in the Thyreos capsule considering these effects.

Thus, medicinal plants, amino acids and minerals contained in the drug Thyreos, take part in the improving of the thyroid gland functioning due to the content of direct precursors of hormone synthesis and various components that synergistically have their effects.

So, the question of the treatment of patients with subclinical hypothyroidism on the background of AIT remains open, because there is no unequivocal position in the consensus on this issue. In addition, in the replacement hormonal treatment of overt hypothyroidism, when the TSH level is close to the upper limit of the reference values, the doctor is faced with the problem of increasing the dose of L-thyroxine, which under these conditions can lead to overdose and the development of symptoms. In this aspect, the use of Thyreos seems promising considering its potential effectiveness in the treatment of hypothyroidism.

In respect that there is the lack of a single point of view on the treatment of AIT and subclinical hypothyroidism, it is reasonable to conduct a study to evaluate the effectiveness of the combined natural remedy Thyreos in terms of its composition.

Accordingly, the purpose of this study was to determine the effectiveness of the drug Thyreos in the treatment of AIT without dysfunction, at the stage of subclinical hypothyroidism as a single therapy and in the treatment of overt hypothyroidism in combination with L-thyroxine.

Material and methods

49 patients with AIT were under observation, mean age 48.26 ± 13.52 years. AIT was diagnosed on the background of the presence of elevated titers of thyroid peroxidase antibodies (AbTPO) and diffuse changes during ultrasound examination (US). All patients were divided into 3 groups. Group 1 included 20 patients with AIT without dysfunction, group 2 included 16 patients with newly diagnosed subclinical hypothyroidism, group 3 included 13 patients who had previously received L-thyroxine therapy for overt hypothyroidism. All patients were prescribed Thyreos 1 capsule twice a day for a period of 3 months as a single therapy (patients of 1st and 2nd groups) or in addition to existing hormone replacement therapy (persons of 3rd group). The clinical characteristics of patients are shown in table 1.

Examination of patients included assessment of complaints (primarily, weakness, fatigue, dry skin, hair loss and brittleness, weight gain), medical history (duration of AIT and hypothyroidism, previous therapy), objective examination data (including the dynamics of weight and body mass index, the condition of the skin and the presence of edema). Laboratory and instrumental examination included the usual set of tests available to the doctor in every outpatient department: TSH, T3, T4, T3, T4, AbTPO, thyroid US. All examinations were performed at the first visit and re-evaluated 3 months after completion of therapy.

In the statistical analysis of the data, the verification
of the distribution of quantitative characteristics for compliance with Gauss’s law was performed by calculating the indicators of asymmetry and excess. Database formation are performed in Excel. The established data of clinical and hormonal-immunological researches are analyzed by methods of parametric and nonparametric statistics. An in-depth determination of statistically significant differences between groups was performed using the Wilcoxon criterion (W). To assess the association between the trait and the compared groups, the criterion \( \chi^2 \) was used, taking into account the number of degrees of freedom (df). The results obtained are presented in the tables as \( n; M \pm m; Me [\text{Min–Max}] \), where \( n \) is the number of observations, \( M \) is the arithmetic mean, \( m \) is the mean deviation, \( Me \) is the median, Min is the minimum value of the indicator in the sample, Max is the maximum value of the indicator in the sample.

**Results**

The effectiveness of Thyreos therapy was evaluated separately for each group, taking into account the data obtained before treatment and after 3 months of treatment.

At the first stage, the analysis of complaints was conducted.

Although complaints of weakness, fatigue, dry skin, dryness and hair loss are more prevalent in patients with uncompensated hypothyroidism, they were quite common in all examined patients. After 3 months of therapy, weakness and rapid fatigue were observed in a significantly smaller number of patients in all three groups: in the 1\(^\text{st} \) group — \( p = 0.000 \) (df = 1; \( \chi^2 = 11.396 \)), in the 2\(^\text{nd} \) group — \( p = 0.013 \) (df = 1; \( \chi^2 = 6.125 \)), in the 3\(^\text{rd} \) group — \( p = 0.044 \) (df = 1; \( \chi^2 = 4.062 \)). After 3 months of therapy with Thyreos also there was probably less patients with complaint of dryness and hair loss in first two groups: \( p = 0.034 \) (df = 1; \( \chi^2 = 4.514 \)) in patients from 1\(^\text{st} \) group and \( p = 0.031 \) (df = 1; \( \chi^2 = 4.664 \)) in persons who were involved in the 2\(^\text{nd} \) group. At the same time, in patients with AIT with overt hypothyroidism who received therapy with Thyreos on the background of previously prescribed hormone replacement therapy with L-thyroxine, there was only a tendency to reduce the prevalence of hair problems: \( p < 0.1 \) (df = 1; \( \chi^2 = 2.462 \)). As a result of treatment, dry skin was significantly reduced in patients of only the 1\(^\text{st} \) study group (df = 1; \( \chi^2 = 5.104; p = 0.024 \)). Thus, the probable positive dynamics of complaints is demonstrated in the 1\(^\text{st} \) group (without thyroid dysfunction).

In the second stage, the indicators of hormonal status were analyzed (data are presented in table 2).

**Table 1. Clinical characteristics of patients with AIT**

| Group       | Average age, years | Sex  | Duration of AIT, years |
|-------------|--------------------|------|------------------------|
| Group 1 (n = 20) | 49.80 ± 3.17     | F — 18 M — 2 | 1.43 ± 0.49           |
| Group 2 (n = 16)  | 49.12 ± 2.89     | F — 15 M — 1 | 1.45 ± 0.72           |
| Group 3 (n = 13)   | 44.31 ± 4.23     | F — 11 M — 2 | 6.01 ± 1.79           |

**Table 2. Dynamics of hormonal parameters in patients with AIT**

| Group       | TSH, mIU/l | T\(_4\) free, pmol/l |
|-------------|------------|----------------------|
|              | Initial level | After treatment | Initial level | After treatment |
| Group 1 (n = 20) | 1.57 [0.04–3.7] | 1.18 [0.4–2.8] | 13.19 [1.01–17.07] | 15.22 [2.12–23.01] |
|              | P > 0.05 | P > 0.05          |
| Group 2 (n = 16)  | 6.20 [4.20–9.36] | 3.90 [0.70–6.90] | 11.90 [0.87–22.23] | 11.15 [1.01–28.10] |
|              | P = 0.003 | P > 0.05          |
| Group 3 (n = 13)   | 3.58 [1.35–8.13] | 1.90 [0.80–15.00] | 10.90 [2.00–15.49] | 15.50 [1.36–19.60] |
|              | P = 0.033 | P = 0.015          |

**Discussion**

In patients of the 1\(^\text{st} \) group, hormonal parameters did not change significantly, which is due to their initially normal levels in this cohort of patients and the lack of effect of the study drug on unchanged thyroid function.

In patients with newly diagnosed subclinical hypothyroidism, significant dynamics of TSH was determined, which was the expected result of the use of Thyreos. It should be noted that before the treatment of TSH > 4.0 mIU/l was determined in all patients of the 2\(^\text{nd} \) group, while after taking thyroid — in 7 patients (43.75 \%).

In patients with overt hypothyroidism, the addition of Thyreos to L-thyroxine significantly reduced TSH levels and increased T\(_4\)-free levels without hormone replacement therapy, which is probably due to the direct stimulatory effect of the drug components on thyroid function.

A measure of the activity of the autoimmune process in the thyroid gland is the titer of AbTPO, the initial level of which was increased in all examined patients. In the dynamics of observation, a decrease in this indicator was found.
in 85% of patients, but the degree of positive effect of Thyreos on autoimmune aggression against normal thyroid cells requires further study involving a larger number of patients and extending the observation period.

It is difficult to judge the dynamics of structural changes in the thyroid gland according to US due to the inability to significantly improve the condition of the body for 3 months of taking the drug. Theoretical analysis of the complex effect of the components of Thyreos on most links of the pathogenesis of AIT suggests the possibility of its positive effect not only on function but also directly on the thyroid tissue. All examined patients tolerated the drug well. No side effects or symptoms of overdose were observed during 3 months of use of Thyreos.

Conclusions

1. In the presence of subclinical and overt hypothyroidism on the background of AIT the use of a combined natural remedy with a complex mechanism of action, which has the effect of stimulating thyroid function — Thyreos is quite justified.

2. SHIVMED’s Thyreos drug, Lactonova nutripharm company production, showed a clinically significant positive effect in AIT, manifested as improved well-being and hormonal status of patients, both in single therapy in case of subclinical hypothyroidism and in combination with L-thyroxine in overt one.

3. Preliminary results on the effect of Thyreos suppression of the autoimmune process in the thyroid gland need further refinement with the involvement of more patients and extension of treatment for more than 3 months.

4. On the background of three months use of Thyreos, no side effects were identified.

Conflicts of interests. Not declared.

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