

The diagnosis and management of primary hypothyroidism

A statement made by the Royal College of Physicians on behalf of

Endorsed by













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Hypothyroidism, underactivity of the thyroid gland, is common. It can make people unwell and should be treated with levothyroxine tablets, a synthetic form of the thyroid hormone thyroxine (also abbreviated to T4). Symptoms of hypothyroidism, for example tiredness, are not specific to underactivity of the thyroid gland, and occur in many other situations. It is important to diagnose hypothyroidism with a blood test, because it can be dangerous to take levothyroxine or other thyroid hormones if they are not needed. We are therefore very concerned that some patients with and without thyroid disease are being inappropriately diagnosed and managed, using levothyroxine and other thyroid hormones, in ways which compromise patient safety. This is potentially an enormous problem, given that, in any one year, one in four of the population have their thyroid function checked.

The vast majority of patients with suspected thyroid disease are supported very well in primary care by their GPs, and their condition, hypothyroidism or otherwise, is appropriately diagnosed and well managed. However, some patients are inappropriately diagnosed as being hypothyroid (often outside the NHS) and are started on levothyroxine or other thyroid hormones, which will not only cause them possible harm, but leaves the true cause of their symptoms undiagnosed and therefore untreated. This statement refers only to primary hypothyroidism. Secondary hypothyroidism is a different condition and should be managed by accredited endocrinologists in the same way as all other diseases of the pituitary gland.

Diagnosis of primary hypothyroidism

- (a) The symptoms of hypothyroidism are very common, both in many other conditions and even in states of normal health. It is therefore essential that thyroid function is tested biochemically alongside a careful clinical assessment of the individual patient. Clinical symptoms and/or signs alone are insufficient to make a diagnosis of hypothyroidism.
- (b) The only validated method of testing thyroid function is on blood, which must include measurement of the levels of thyroid-stimulating hormone (TSH) and free thyroxine (FT4) in serum.
- (c) There is no evidence to support the use of body fluids other than blood (eg urine, saliva) to test for thyroid function, or the measurement of basal body temperature in the diagnosis of thyroid dysfunction.
- (d) The results of blood tests for thyroid function can be influenced by other factors, for example in some illnesses which do not permanently damage the thyroid gland. In this case the tests will return to normal after the illness and thyroid hormone therapy is not needed (and can be harmful).
- (e) We recognise that different methods used for testing blood can give differing results, and we support the international initiative for greater harmonisation of reference ranges and of the units used in expressing results.

Treatment of primary hypothyroidism

- (a) The aim of the treatment of hypothyroidism is to render the patient back to the normal or 'euthyroid' state.
- (b) When a sufficient dose of thyroid treatment is given to lower the TSH to within the normal range (reference range) for the test method used, patients usually recover from their symptoms of hypothyroidism.

- (c) Fine-tuning of TSH levels inside the reference range may be needed for individual patients.
- (d) Patients with continuing symptoms after appropriate thyroxine treatment should be further investigated to diagnose and treat the cause.
- (e) Overwhelming evidence supports the use of thyroxine (T4 or tetra-iodothyronine) alone in the treatment of hypothyroidism, with this usually being prescribed as levothyroxine. We do not recommend the prescribing of additional tri-iodothyronine (T3) in any presently available formulation, including Armour Thyroid, as it is inconsistent with normal physiology, has not been unequivocally proven to be of any benefit to patients, and may be harmful.
- (f) There are potential risks from T3 therapy, using current preparations, on bone (eg osteoporosis) and the heart (eg arrhythmia). We note that the extract marketed as Armour Thyroid contains an excessive amount of T3 in relation to T4. Over-treatment with T4, when given alone, has similar risks.

Treatment of sub-clinical hypothyroidism

- (a) Sub-clinical hypothyroidism is defined as being present in a patient when the TSH is above the upper limit of the reference range (but usually less than 10mU/L) and free T4 levels are within the reference range.
- (b) Some patients with sub-clinical hypothyroidism, particularly those whose TSH level is greater than 10mU/L, may benefit from treatment with levothyroxine in the same way as for clinical hypothyroidism, as indicated in national guidelines (British Thyroid Association, The Association for Clinical Biochemistry, British Thyroid Foundation. *UK guidelines for the use of thyroid function tests*. London, BTA/ACB/BTF: 2006. www.british-thyroid-association.org/info-for-patients/Docs/TFT guideline final version July 2006.pdf).

Patients with normal thyroid function tests

- (a) We recommend that those patients whose thyroid blood tests are within the reference ranges but who have continuing symptoms, whether on levothyroxine or not, should be further investigated for the non-thyroid cause of the symptoms.
- (b) A further opinion or help with these patients may be sought from appropriate specialists on specialist registers of the Royal College of Physicians or the Royal College of Paediatrics and Child Health.

Conclusion

- (a) Patients with suspected primary hypothyroidism should only be diagnosed with blood tests including measurement of serum TSH.
- (b) Patients with primary hypothyroidism should be treated with T4 using levothyroxine tablets (listed in the British National Formulary) alone.
- (c) There is no indication for the prescription of levothyroxine or any preparation containing thyroid hormones to patients without an established diagnosis of thyroid disease and thyroid blood tests within the reference ranges.
- (d) In patients with suspected primary hypothyroidism there is no indication for the prescription of levothyroxine or any preparation containing thyroid hormones to patients with thyroid blood tests initially within the normal range. Thus

patients with normal levels of T4 and TSH do not have primary hypothyroidism, and even if they have symptoms which might suggest this, they should not be given thyroid hormone replacement therapy.

- (e) The RCP does not support the use of thyroid extracts or levothyroxine and T3 combinations without further validated research published in peer-reviewed journals. Therefore, the inclusion of T3 in the treatment of hypothyroidism should be reserved for use by accredited endocrinologists in individual patients.
- (g) Laboratories which measure thyroid function in other bodily fluids besides blood need to provide analytical and clinical validation to demonstrate their efficacy.
- (h) The above statements reflect best practice of clinical endocrinologists accredited by the Royal College of Physicians and the Royal College of Paediatrics and Child Health.

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