

21 million Americans may take a hypothyroidism drug they don't need

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As many as 90% of those who take levothyroxine [Synthroid] may have been unnecessarily prescribed the hypothyroidism medication.

Approximately 23 million Americans take levothyroxine, making it one of the most prescribed drugs in the country. To test for hypothyroidism (underactive thyroid), clinicians measure the levels of thyroid-stimulating hormone (TSH) and free thyroxine (Free T4).

However, new research points to natural [seasonal variation](#) in these hormones that current laboratory testing does not take into account. This is leading to an enormous number of unnecessary levothyroxine prescriptions, and its overuse presents risks to [patients](#), warns Joe El-Khoury, Ph.D., associate professor of laboratory medicine, in a letter published in *Clinical Chemistry* on March 1.

"The emerging evidence is very concerning because we're actively giving patients a drug that they don't need that can have potentially [severe side effects](#), especially in elderly individuals over 80," says El-Khoury.

How hypothyroidism is diagnosed

Patients suffering with hypothyroidism may experience symptoms including fatigue and depression, and in extreme cases, the condition can be debilitating. Providers diagnose hypothyroidism by first measuring TSH levels in the blood. If the level is elevated, they will conduct a second test examining Free T4 levels. If TSH is high and Free T4 is low, the provider diagnoses the patient with hypothyroidism. Levothyroxine works by supplementing the low hormone levels with exogenous T4.

Some patients, however, have mildly elevated TSH and normal Free T4. Providers diagnose this as subclinical hypothyroidism, and sometimes this is also treated with levothyroxine to lower TSH. This practice may do more harm than good. "Study after study has shown that there is greater risk when you overtreat with levothyroxine in patients who may not need it," says El-Khoury.

A 2021 study including collaborators from Yale School of Public Health, Mayo Clinic, and University of Arkansas found that out of the 23 million Americans who are actively taking levothyroxine, approximately 21 million [~90%] likely don't need the prescription. Because levothyroxine can cause side effects including anxiety, heat intolerance, and diarrhea—and in extreme cases, cardiovascular morbidity and death, especially in those over 80—this finding is alarming, says El-Khoury.

Diagnosing hypothyroidism may depend on the season

According to El-Khoury, a major reason for inappropriate diagnoses is seasonal variation. Typically, TSH is higher in the winter. This is also when more people may experience symptoms of seasonal affective disorder (SAD), which can have symptoms similar to hypothyroidism. Because current screening measures do not consider the natural variation, many patients presenting with [hypothyroidism](#)-like symptoms are getting tested at a time when their TSH levels are naturally higher and being prescribed levothyroxine. "But if many of those same people had gotten the same test a few months later, it would have come back as normal," says El-Khoury.

El-Khoury hopes to raise awareness about the extent of this problem and encourage providers to re-test their patients at least 3 months later before initiating levothyroxine treatment. Furthermore, he believes that the American Thyroid Association and such laboratory organizations as the American Association for Clinical Chemistry's AACC Academy need to carefully consider and agree on a clinical decision limit for TSH.

The assay used at Yale defines the normal limit for TSH as between 0.27 and 4.2 mIU/L. However, recent research suggests that levothyroxine has no benefit in patients who initiate treatment when their levels are naturally under 7.0 mIU/L. "This evidence needs to be reviewed and agreed upon by these medical associations so that we can make changes

nationally and perhaps even internationally," he says.

To many, raising the limit from 4.0 mIU/L to 7.0 mIU/L may seem like a big change. However, the emerging findings highlight that the currently accepted range is no longer backed by evidence and the need exists to reevaluate the existing literature. "TSH has such high biological variability that we have not taken into account for so many years," says El-Khoury. "We need to reexamine what we thought to be normal."

For patients currently taking levothyroxine, El-Khoury urges them not to stop taking levothyroxine without consulting a medical professional. "Ask your doctor if [levothyroxine](#) is really right for you, if your TSH value was less than 7 mIU/L when treatment was initiated," he says.

More information: Joe M El-Khoury, Seasonal Variation and Thyroid Function Testing: Source of Misdiagnosis and Levothyroxine Over-Prescription, *Clinical Chemistry* (2023). [DOI: 10.1093/clinchem/hvad017](#)

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