Thyroid Medications:

Q & A with Mary Parks, M.D.

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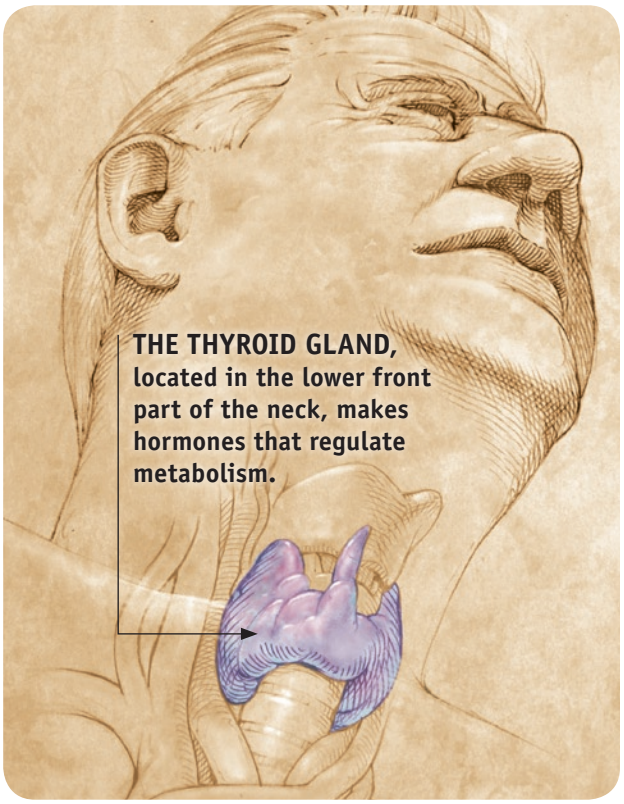
January is Thyroid Awareness Month



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Q. What is thyroid dysfunction?

A. Thyroid dysfunction occurs when the thyroid gland isn't working properly. Located in the lower front part of the neck, the thyroid gland makes hormones that regulate metabolism--chemical processes in the body that affect how we use energy. When the thyroid gland produces too much hormone, it's known as hyperthyroidism or overactive thyroid. When this gland doesn't produce enough hormone, it's known as hypothyroidism or underactive thyroid.

Q. How can thyroid dysfunction affect the body?

A. When the thyroid gland doesn't work properly, it affects how many of our organs function, including the brain, heart, kidneys, liver, and skin. An overactive thyroid can cause symptoms such as heat intolerance, weight loss, menstrual problems, muscle weakness, fatigue, heart palpitations, and tremors. Hyperthyroidism can also lead to osteoporosis. Symptoms of an underactive thyroid can include weight gain, fatigue, depression, mood swings, dry hair and skin, and constipation. Hypothyroidism is also associated with increased cholesterol levels which may increase the risk of cardiovascular disease.

Q. What medications are approved to treat hyperthyroidism?

A. Two drugs are approved by FDA for treating overactive thyroid—propylthioracil (PTU) and methimazole (Tapezole.) These tablets work by slowing down the production of thyroid hormone. They are usually given in three equal doses about 8 hours a part. Common side effects can include skin rash, upset stomach, and drowsiness. More serious side effects are rare, but can include sore throat, fever, chills, jaundice (yellowing of the skin or eyes), decreased white blood cells, and liver disease.

Other treatment options for hyperthyroidism include surgery and radioactive iodine. Sometimes anti-thyroid drugs are used in conjunction with radioactive iodine, a therapy that reduces the production of thyroid hormone. This treats the problem of overactive thyroid, but usually results in the patient having an underactive thyroid, which also requires treatment.

In addition to some of the therapies discussed above, some physicians may co-prescribe a medication called a beta-blocker to treat some of the symptoms of hyperthyroidism (e.g., heart palpitations, tremor) until the hyperthyroidism is effectively managed.

Q. What medications are approved to treat hypothyroidism?

Patients should talk with their doctors about which drug is right for them.

A. Medications for underactive thyroid work by replacing hormone that's missing. The approved medication for this indication is levothyroxine sodium, which is identical to the natural thyroid hormone produced by the body. Examples of brand names for levothyroxine are Synthroid, Levoxyl, and Levothroid. These drugs may also be used in the management of thyroid cancer or other thyroid conditions. Tablets are usually taken once a day. Side effects mostly occur because of overdosage of the medication and can include nervousness, weight loss, rapid heart beat, irritability, and anxiety. Most patients with underactive thyroid need to take levothyroxine for a lifetime to maintain proper hormone levels. The safety of long-term use of levothyroxine is well-documented; however, patients need to have routine laboratory tests to be certain that the correct dose is prescribed for the underlying condition.

Q. How would patients know if they are not getting the right dose of thyroid medication?

A. Thyroid medications require close monitoring because precise dosing is critical for effective control of hormone levels. Physicians make sure patients get the correct dose of medicine by performing physical examinations and regularly checking thyroid stimulating hormone (TSH) levels through simple blood tests. Patients should also communicate any symptoms to their doctor.

Q. What should patients know about choosing or switching thyroid medications? Are generics as effective as brand name medications?

A. Patients should talk with their doctors about which drug is right for them. Approved generic thyroid medications are as effective as brand name medications. There have been concerns raised from physicians and patients about varying product performance of levothyroxine sodium, particularly after refills that may involve different products from different manufacturers. But we've found that this may not be related to generic versus brand. Recently, manufacturers (brand and generic) have provided FDA with data revealing that some products lose their potency over time. This loss in potency may account for some of the variable effects with certain products, whether brand or generic.

Q. What action has FDA taken to improve the quality of levothyroxine sodium products?

A. In 2005, FDA held a public meeting with the American Thyroid Association, the Endocrine Society, and the American Association of Clinical Endocrinologists. Some endocrinologists expressed concern about the performance of these products. As a result, FDA requested product stability data from manufacturers of all approved products manufactured between July 2003 and June 2005. Then in 2006, FDA presented the data at a joint meeting of the Endocrine and Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Sciences. The purpose of the meeting was to discuss the potency and stability of marketed levothyroxine products. In October 2007, FDA announced that it is tightening its potency specifications for all levothyroxine sodium to ensure the drug retains its potency over its entire shelf life.

Q. What can patients do to ensure proper use of thyroid medications?

A. • Store these medicines in a dry place at room temperature and avoid bathrooms and other humid, hot environments because these speed up deterioration of levothyroxine sodium.

• Read drug labels carefully and follow directions. Taking thyroid medications inconsistently can interfere with treatment. They should be taken at about the same time every day.

• Keep your doctor informed about all prescription and non-prescription medications you are taking, including dietary supplements. For example, antacids and vitamins can interfere with the absorption of levothyroxine. Levothyroxine can also increase the effects of blood thinners.

• Keep your doctor informed of how you are feeling and any side effects you may be experiencing. FDA

For More Information

American Association of Clinical Endocrinologists
www.thyroidawareness.com

Consumer Update: Ensuring Potency of Thyroid Drugs
www.fda.gov/consumer/updates/thyroiddrugs101207.html

Table of Approved Levothyroxine Sodium Oral Formulations (Tablet or Capsule)
www.fda.gov/cder/drug/infopage/levothyroxine/table.htm