



HYPOTHYROIDISM

Generic and branded levothyroxine preparations are not the same in children with congenital hypothyroidism

BACKGROUND

Hypothyroidism is treated by thyroid hormone replacement therapy, usually in the form of levothyroxine. There are branded levothyroxine preparations (ie Synthroid™, Levoxyl™) as well as generic preparations. While the FDA has deemed generic and branded preparations equal, this has been based on short-term studies in healthy adult volunteers and not long-term treatment of hypothyroid patients. In infants with severe congenital hypothyroidism, even small changes in thyroid hormone levels may have negative effects on their development. Few clinical studies have been performed to date to determine whether generic and branded levothyroxine preparations are truly equal in patients with hypothyroidism. In this study, generic and branded levothyroxine preparations are compared as treatment in a group of hypothyroid children.

THE FULL ARTICLE TITLE

Carswell JM et al. Generic and brand-name L-thyroxine are not bioequivalent for children with severe congenital hypothyroidism. *J Clin Endocrinol Metab.* December 21, 2012.

SUMMARY OF THE STUDY

This study evaluated 31 children and adolescents 3 to 18 years of age with known hypothyroidism (serum TSH concentration at diagnosis, >100 mIU/L). A total of 20 of the children had congenital hypothyroidism, while the rest had Hashimoto's thyroiditis as the cause of their hypothyroidism. The children were assigned to receive their usual levothyroxine dose as either Synthroid™ (Abbott Laboratories) or generic levothyroxine (Sandoz) for 8 weeks and then were switched to the other preparation for 8 weeks. Serum TSH, free T₄, and total T₃ were measured at the end of each 8 week treatment period were compared for

each subject.

The serum TSH was significantly lower (0.7 mIU/L vs. 1.8 mIU/L) after 8 weeks of Synthroid™ than after 8 weeks of the generic levothyroxine. This difference did not depend on age and was seen only in children with congenital hypothyroidism. In the children with Hashimoto's disease, TSH did not differ between branded and generic levothyroxine. There were no differences in free T₄ or total T₃ following each treatment period.

WHAT ARE THE IMPLICATIONS OF THIS STUDY?

This study demonstrates that Synthroid and generic levothyroxine are not equal in children with congenital hypothyroidism, even though the FDA states they are interchangeable. This difference was not observed in patients with Hashimoto's thyroiditis, possibly because they have an intact thyroid although it is not working. The results in the children with congenital hypothyroidism may possibly be seen in other patients (such as those with thyroid cancer) who have had a thyroidectomy. In any event, this study reinforces the need for checking thyroid tests to adjust the dose when the levothyroxine preparations are being changed. Further studies with larger number of patients would be helpful to confirm these results.

— M. Regina Castro, MD

ATA THYROID BROCHURE LINKS

Hypothyroidism: <http://www.thyroid.org/what-is-hypothyroidism>

Thyroid Function Tests: <http://www.thyroid.org/blood-test-for-thyroid>

Thyroid Hormone Treatment: <http://www.thyroid.org/thyroid-hormone-treatment>

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HYPOTHYROIDISM, continued

ABBREVIATIONS & DEFINITIONS

Hashimoto's thyroiditis: the most common cause of hypothyroidism in the United States. It is caused by antibodies that attack the thyroid and destroy it.

Hypothyroidism: a condition where the thyroid gland is underactive and doesn't produce enough thyroid hormone. Treatment requires taking thyroid hormone pills.

Hashimoto's thyroiditis: the most common cause of hypothyroidism in the United States. It is caused by antibodies that attack the thyroid and destroy the gland.

Congenital hypothyroidism: thyroid hormone deficiency (hypothyroidism) present at birth.

Thyroidectomy: surgery to remove the entire thyroid gland. When the entire thyroid is removed it is termed a total thyroidectomy. When less is removed, such as in removal of a lobe, it is termed a partial thyroidectomy.

Levothyroxine (T₄): the major hormone produced by the thyroid gland and available in pill form as LevoxyTM, SynthroidTM, LevothroidTM and generic preparations.

Thyroid hormone therapy: patients with hypothyroidism are most often treated with Levothyroxine in order to return their thyroid hormone levels to normal

Thyroxine (T₄): the major hormone produced by the thyroid gland. T₄ gets converted to the active hormone T₃ in various tissues in the body.

Triiodothyronine (T₃): the active thyroid hormone, usually produced from thyroxine.

TSH: thyroid stimulating hormone – produced by the pituitary gland that regulates thyroid function; also the best screening test to determine if the thyroid is functioning normally.