

ENDOCRINE

Amount of Testosterone on Laundered Clothing After Use of Testosterone Topical 2% Solution by Healthy Male Volunteers



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ABSTRACT

Introduction: Testosterone 2% solution (Axiron) applied to armpit(s) is used for replacement therapy in men with a deficiency of endogenous testosterone.

Aim: To determine the amount of testosterone on subjects' T-shirts 12 hours after applying testosterone solution, the residual testosterone on subjects' T-shirts after laundering, and the testosterone transferred to unworn textile items during laundering with worn T-shirts.

Methods: Healthy males ≥ 18 years old applied 2×1.5 mL of testosterone 2% solution to both axillae (total testosterone dose: 120 mg) and dressed in cotton long-sleeved T-shirts after a ≥ 3 -minute waiting period. T-shirts were worn 12 hours before being removed and cut into halves, after which a 10×10 cm sample of each armpit area was excised for testosterone quantification before or after laundering with samples of unworn textiles.

Main Outcome Measures: Testosterone on worn T-shirts before and after laundering, and on unworn textiles laundered with the worn T-shirts.

Results: Twelve subjects enrolled and completed, with only minor adverse events. Mean testosterone in unwashed worn T-shirts was 7603 μg , with high between-subject variability (3359 μg to 13,069 μg), representing 13% of the dose to 1 armpit. Mean testosterone in worn, laundered T-shirts was 260 μg (7.55 μg to 1343 μg), representing 3% of the dose to 1 armpit. Mean transferred testosterone to other textiles during laundering ranged from 69 μg on texturized Dacron 56T Double to 10,402 μg on 87/13 nylon/Lycra knit, representing 0.0382% to 5.78% of the dose to 1 armpit.

Conclusion: Thirteen percent of the testosterone applied to axillae was transferred to T-shirts during wear. Ninety-seven percent of the transferred testosterone was removed from the T-shirts during washing, some of which was then absorbed to various degrees by other textiles. Clinical implications of these findings and biological activity of the remaining/transferred testosterone are unknown.

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Key Words: Testosterone; Clothing; Transfer; Environmental Exposure

INTRODUCTION

Testosterone topical 2% solution (Axiron) — hereafter referred to as testosterone solution — is approved for replacement therapy in men for conditions associated with a deficiency or absence of endogenous testosterone, primary hypogonadism, and hypogonadotropic hypogonadism.¹ Patients are advised to apply testosterone solution topically to both axillae from a metered

pump device that dispenses 1.5 mL of the solution, which contains 30 mg of testosterone. It is recommended that patients start treatment with a dose of 1.5 mL applied to each axilla, for a total testosterone dose of 60 mg. Based on an individual patient's clinical results, the dose can be increased to a maximum of 2×1.5 mL applied to each axilla (for a total testosterone dose of 120 mg) or reduced to 1.5 mL applied to only 1 axilla (for a total testosterone dose of 30 mg).¹

Secondary exposure of women and children from patients receiving transdermal testosterone replacement therapy with testosterone gels has been reported.² Clinically significant changes can occur in women and children exposed to testosterone through accidental transfer.^{3–8} Ronde reviewed the reports of accidental exposure to topical testosterone, from both published and unpublished cases. In most events, the cause of

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transfer was attributed to direct skin-to-skin contact. However, in 2 cases, potential exposure to testosterone via shared bed sheets or a towel was postulated.⁸ This indicates a belief in the potential for transfer of testosterone via means other than direct contact with treated skin. Patients using testosterone 2% solution are advised to apply testosterone solution only to the axillae and, to limit the potential for secondary exposure of others, to cover the application site with clothing after waiting for 3 minutes for the solution to dry.¹ It is unknown to what extent testosterone applied as a 2% solution might transfer to clothing that comes in contact with the application site. In addition to the question of how much testosterone may transfer to clothing worn by the patient, individuals receiving treatment with testosterone solution as well as their family members have also asked if testosterone could be transferred to other textiles during laundering.

AIMS

The primary objective of this study was to determine the amount of testosterone on subjects' T-shirts worn for 12 hours after applying testosterone solution equivalent to 120 mg testosterone. Secondary objectives were to measure the remaining amount of testosterone on subjects' T-shirts after laundering and to assess the amount of testosterone on unworn textile items laundered with the worn T-shirts.

METHODS

This was a phase 1, open-label, single-dose, single-period study in healthy males to determine the amount of testosterone present on unlaundered and laundered clothing after normal use of testosterone solution. The study protocol was reviewed and approved by the applicable organizational ethical review board. Subjects provided written informed consent before undergoing any study procedures, and the study was conducted in accordance with the ethical principles of the Declaration of Helsinki, Good Clinical Practice, and applicable laws and regulations.

Subjects

Healthy men ≥ 18 years of age were enrolled in the study. Excluded were men who had used any of the following: topical testosterone replacement therapy within 3 months before study entry, parenteral testosterone replacement within 30 days before screening, long-acting intramuscular testosterone undecanoate within 6 months before screening, or testosterone pellets within 12 months before screening.

Study Design

Subjects were screened up to 28 days before dosing. On the morning of day 1, subjects applied two 1.5 mL doses of testosterone solution to both axillae (total testosterone dose: 120 mg, as 60 mg per axilla; [Figure 1](#)). After waiting for at least

3 minutes for the testosterone solution to dry, subjects put on a fresh pre-laundered cotton T-shirt (Hanes Adult Beefy-T Long Sleeve T-Shirt [plain white]) 1 size smaller than the subjects' usual sizes to maximize contact between the T-shirt material and the application site. Subjects were instructed to not use any deodorant, antiperspirant, or body lotion on the application site on the day of dose application until after the T-shirts were collected at the end of the study. During the study, subjects were confined to an air conditioned clinical research unit in the United States, and were prohibited from engaging in strenuous physical activity.

The T-shirts were worn for 12 hours continuously post-dosing, after which the subjects' T-shirts were collected for testosterone analysis. T-shirts were cut in half, and one half of each T-shirt was air-dried, individually packed in a Ziploc plastic bag, and submitted to the laboratory where a 10×10 cm ($\sim 4 \times 4$ inch) sample of the armpit area was excised for testosterone extraction and quantification. The other half of each T-shirt was washed with Tide Free & Gentle detergent and tumble-dried in batches of 3 T-shirt halves per load with pre-washed, unworn 91×91 cm (36×36 inch) textile samples of various fabric types (bleached cotton terry cloth, wool jersey knit fabric, 56/44 cotton/linen, texturized Dacron 56T Double, and 87/13 nylon/Lycra Knit; Testfabrics, Inc, West Pittston, PA, USA). The textiles were chosen to represent the classes of popular plant-based (cotton and linen), animal hair-based (wool), and synthetic (Dacron, nylon and Lycra) fabrics. A standard domestic washing machine (Whirlpool Duet [washer/GHW9150PW4]; program/cycle: normal/casual with soil level as "normal," water temperature as "warm/cold" and spin speed as "high") and dryer (Whirlpool Duet [dryer/WED9750WW1]; cycle: normal; temperature: medium; dryness level: normal) were used.

From each of the worn, washed T-shirt halves, a 10×10 cm sample of the armpit area was excised for testosterone extraction and quantification. From each of the unworn textiles washed with the worn T-shirt halves, a 10×10 cm fabric sample was excised for testosterone extraction and quantification.

Each intact unworn textile item and T-shirt half was weighed at the laboratory before samples were removed and each excised sample was weighed before analysis.

Analysis Methods

The T-shirt and textile samples were analyzed for testosterone content using qualified methods at Covance Laboratories, Inc (Madison, WI, USA). A low-range (20 ng to 20,000 ng per 10×10 cm sample) or a high-range (15 μg to 6,000 μg per 10×10 cm sample) qualified method was used to analyze study samples, as appropriate. Testosterone was extracted from the samples with ethanol. The extract was fortified with a deuterium-labeled testosterone (testosterone- d_5) internal standard and analyzed using liquid chromatography (LC) with tandem mass spectrometric detection (MS/MS). The method was qualified for use by

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