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JOURNAL ARTICLE

# Testosterone release from a subcutaneous, biodegradable microcapsule formulation (Viatrel) in hypogonadal men

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Men with hypogonadism require testosterone replacement for optimal health. In the United States, testosterone is currently administered by daily transdermal patches, topical gels or intramuscular injections every 1-3 weeks. Biodegradable polylactide-co-glycolide microcapsules are currently used for long-term drug delivery in humans. Such microcapsules that contain testosterone could provide a better means of long-term testosterone therapy. We therefore studied the pharmacokinetics and pharmacodynamics of testosterone release from testosterone microcapsules in men with hypogonadism. Fourteen men who had been treated previously with testosterone were enrolled in an open-label, prospective study of testosterone microcapsule administration. Subjects were enrolled if 2 consecutive serum total testosterone levels were lower than 8.7 nmol/L after a 4-week washout from testosterone therapy. Subjects were injected with a single dose of either 267 mg (n = 7) or 534 mg (n = 7) of (Viatrel) testosterone microcapsule, and serum total testosterone, dihydrotestosterone, estradiol, sex-hormone binding globulin, luteinizing hormone, and follicle-stimulating hormone levels were determined at days -14, -7, and 0 before the injection; at days 1, 2, and 7 after the injection; and then weekly thereafter for 8-12 weeks. Mean serum total testosterone levels peaked immediately following injection on day 1 at 25.2 +/- 2.6 nmol/L in the 267 mg group and 34.7 +/- 2.4 nmol/L in the 534 mg group. Total serum testosterone levels declined gradually and fell below 8.7 nmol/L at 42 days after injection in the 267 mg group, and 70 days after injection in the 534 mg group. Estradiol and dihydrotestosterone levels followed a similar pattern. Mean serum free testosterone also peaked immediately following injection on day 1 at 0.51 +/- 0.05 nmol/L in the 267 mg group and 0.97 +/- 0.08 nmol/L in the 534 mg group. No significant adverse reactions were seen, although 2 subjects complained of transient tenderness and fullness at their injection sites. We conclude that a single injection of 534 mg of testosterone microcapsules to men with hypogonadism normalizes serum hormone levels for up to 10-11 weeks, albeit with a pronounced early peak and a relatively long period of low-normal serum total testosterone. Subcutaneously administered testosterone microcapsules may provide a safe and convenient method for the long-term treatment of male hypogonadism or testosterone replacement in male contraceptive regimens.

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