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Oral Testosterone in Oil: Pharmacokinetic Effects of 5α Reduction by Finasteride or Dutasteride and Food Intake in Men

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Oral administration of 400 mg of testosterone (T) in oil, when combined with the 5α reductase inhibitor dutasteride (D), elevates serum T in medically castrated men to the normal range. In this study, we sought to determine the impact of 1) finasteride (F) and 2) food intake on the serum T and dihydrotestosterone (DHT) levels observed after the oral administration of T in oil. Therefore, we conducted a pharmacokinetic study of oral T in oil, alone or with D or F, in the fasting and fed states in normal men whose endogenous T production was suppressed by the GnRH antagonist acyline. After acyline administration, 7 healthy men (mean age 31 ± 8 years) were sequentially administered five 400-mg doses of oral T in sesame oil once daily. The first dose of oral T (T-alone) in oil was given while fasting without F or D. The second (fasting) and third (fed) doses were administered after pretreatment with F (T + F). Four days later, the fourth (fasting) and fifth (fed) doses were administered after pretreatment with D (T + D). Blood samples for measurement of serum T and DHT were obtained before T dosing and 0.5, 1, 2, 3, 4, 6, 8, 10, 12, and 24 hours after each administration. In the fasting state, 24-hour area-under-the-curve of serum T after oral T administration was significantly greater with coadministration of either D or F compared with T-alone (126 ± 36 nmol-h/L [T-alone] vs 287 ± 98 nmol-h/L [T + F] vs 236 ± 82 nmol-h/L [T + D]; $P < .05$ for T + F and T + D vs T-alone). Administration of the T with food nonsignificantly decreased serum T levels compared with fasting administration. The administration of oral T in oil combined with either F or D results in serum T levels adequate to treat men with testicular failure. Additional studies of the combination of oral T in oil with 5α-reductase inhibitors as a novel form of oral T therapy are warranted.

Key words: Androgen, hypogonadism, metabolism, acyline

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