Study Design

Materials and Methods

case and number of patients are controlled

variations in patient restoration dose where the total

and then, JTH, FSH, and SHBG levels attained in the
case we studied restoration under the formula.

ESOSTERONE has been used for restoration to

AimetT: We studied the pharmacokinetics and performance

Testosterone Prolactin in Man

Pharmacokinetics and Pharmacodynamics of

(c) 1990 by The Endocrine Society.

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Authors: D. J. ANDREW, A. N. CONWAY, AND I N. BOWLAN.

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Abstract

Testosterone pellets in man:

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Pharmacia and Coenzyme

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TABLE 1: Clinical features of hypogonadal men

<table>
<thead>
<tr>
<th>Condition</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary hypogonadism</td>
<td>50%</td>
</tr>
<tr>
<td>Secondary hypogonadism</td>
<td>25%</td>
</tr>
<tr>
<td>Mixed hypogonadism</td>
<td>25%</td>
</tr>
</tbody>
</table>

**Results**

The clinical features of hypogonadal men are expressed as mean and SD. The levels of testosterone were significantly lower in men with hypogonadism compared to normal controls. The mean testosterone levels were 3.5 ± 0.8 ng/dL in hypogonadal men and 8.5 ± 2.0 ng/dL in normal controls. The difference was statistically significant (p < 0.05).

**Discussion**

The results of this study indicate that testosterone levels are lower in hypogonadal men, which is consistent with previous studies. The cause of low testosterone levels in hypogonadal men is multifactorial, and further research is needed to understand the underlying mechanisms.
primary and secondary hypogonadism were similar in all three pellet regimens. Maintenance of libido, potency, and well-being was very consistent on all three androgen replacement regimens for 4-5 months on the protocol. No significant differences in treatment effects were noted among treatments. The remainder expressed preferences for parenteral testosterone ester injections or no preferences.}

Pharmacokinetics—total and free testosterone

All three pellet regimens gave highly predictable time courses for total and free testosterone levels with a clear dose-response relationship between pellet dose and plasma testosterone levels. Plasma testosterone levels peaked at the first month and gradually declined to return to baseline by 6 months after the 600 mg dose regimen but remained significantly elevated after

Net testosterone release (area-under-curve of testosterone release vs. time plot) was highly correlated with pellet dose (r = 0.999) with the 1200 mg dose (130.1 arbitrary units) giving the highest release that of either 600 mg or 300 mg. Net testosterone release also correlated with total surface area of the pellets (r = 0.990). The net bioavailable testosterone was also highly correlated with both total pellet dose (6 x 100 mg = 180 mg) and SHBG (r = -0.44), BSA (r = 0.46), and DBW (r = -0.25, all P < 0.001).

Pharmacokinetics—adsorption kinetics

Plasma free testosterone was highly correlated with plasma total testosterone (r = 0.90) and therefore free testosterone levels were significantly higher in the first (but not second) 3 months after the 6 x 100 mg regimen compared with the second (P > 0.15) but plasma free T was inversely correlated (r = -0.13, P = 0.004) with SHBG (Fig. 2). Plasma SHBG (Fig. 2) did not vary significantly between pellet regimens (P = 0.06), and SHBG was not correlated with either age or obesity (r = 0.4, P = 0.96).
monkeys. In contrast to the 1200-mg dose produced earlier, the 600-mg dose produced much greater LH levels at 7 and 9 months with a slight rise in FSH levels at 6 months with a significant increase in LH and FSH levels at 1 and 3 months after the 600-mg dose. The 600-mg dose produced higher LH levels at 15, 17, and 19 months than the 200-mg dose (Fig. 4) (P < 0.01 for both LH and FSH). The 600-mg dose produced a higher LH level than the 200-mg dose, and the LH levels were still detectable at 6 months after the 600-mg dose. The LH levels were not detectable at 6 months after the 200-mg dose.

In the present study, the LH levels were measured at 7 and 9 months, and the FSH levels at 6 months. The LH levels were significantly higher in the 600-mg group than in the 200-mg group at 6 months. The FSH levels were also higher in the 600-mg group than in the 200-mg group at 6 months.

In the present study, the LH levels were measured at 7 and 9 months, and the FSH levels at 6 months. The LH levels were significantly higher in the 600-mg group than in the 200-mg group at 6 months. The FSH levels were also higher in the 600-mg group than in the 200-mg group at 6 months.
LH levels between 1 and 4 months with return to baseline levels after 5 months. Nondiabetic men achieved a significant clinical improvement after 3 months with return to baseline levels after 5 months.

Side effects:

Pellet implantation had few side effects. These include mild bleeding, pain, and a transient increase in FSH levels. The frequency of these side effects was comparable to that observed in studies of depot gonadotropins.

Discussion:

This study reports the first detailed pharmacokinetic analysis of testosterone pellets in hypogonadal men. Despite the clinical use of testosterone pellets for 50 years, the pharmacological data have been largely descriptive and have not provided a comprehensive understanding of the clinical efficacy of this form of replacement therapy. This study should provide important insights into the clinical use of testosterone pellets.
The implantation of testosterone pellets produce a highly effective form of androgen therapy. The pellets provide a flexible dosage form with smooth, physiologically sustained androgen suppression and are not associated with the side effects of other testosterone delivery systems. The authors are grateful for the assistance of Michael T. Meston, Department of Psychology, University of Texas, for his expert advice and guidance in conducting the studies.

References