# Medroxyprogesterone and Paraphiles: Do Testosterone Levels Matter?

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**We examine the associations between pretreatment testosterone (TTS) levels and sociodemographic, clinical, and sexual behavioral characteristics. Two groups, low and normal pretreatment TTS, were treated with medroxyprogesterone acetate (MPA) and compared on clinical response (deviant and nondeviant sexual behaviors; recidivism) and length of time to return to pretreatment TTS after discontinuing MPA. Thirteen paraphilic men who were treated with MPA and had TTS levels monitored at approximately three-month intervals during and after MPA were followed naturalistically. The principal outcome measures pertained to TTS levels and data from a self-report psychosexual inventory, which quantified deviant and nondeviant sexual activities. Time to return to baseline TTS levels were analyzed with Kaplan-Meier survival analysis. Nonparametric methods were used to compare the two groups on other variables. Multiple regression was used to examine the contribution of combinations of variables to TTS outcome. Subjects with low pretreatment TTS received MPA for longer periods of time, and older subjects took longer to return to pretreatment TTS levels despite being treated for shorter periods of time. Although subjects with lower pretreatment TTS levels may be more sensitive to MPA's TTS-suppressive effects, the multiple regression analysis showed that age may be an important determinant of the time it takes for TTS levels to return to pretreatment baseline. Sociodemographic, clinical, and self-reported measures of sexual behavior did not distinguish between low and normal TTS level groups. Only one relapse was detected. Further studies with larger samples are required to better understand the role of TTS monitoring of sex offenders treated with MPA, in order to justify its continued use as a measurement of treatment adequacy and to study its potential role as a predictor of treatment outcome.**

Research on the relationship between testosterone (TTS) and behavior suggests that TTS influences sexual functioning.[1,2] Medroxyprogesterone acetate (MPA) is a synthetic progestin with androgen-depleting activity, which is used

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for treating the deviant sexual behavior of male sex offenders.[3–6] Plasma TTS levels are reliably reduced to castrate or prepubescent levels with weekly intramuscular (i.m.) injections of the depot preparation, depo-MPA (Depo-Provera).[7] Studies involving non-sex offender samples have demonstrated a relationship between plasma TTS levels and self-reported sexual fantasies and initiation of sexual activity.[5–10] Among sex offenders, antiandrogens such as MPA consistently have been shown to lower TTS levels along with decrease self-reported deviant sexual drives, fantasies, and behavior.[3, 4, 11–13]

Studies of the relationship between TTS and sexual behavior among non-sex offending men have demonstrated that raising TTS levels increases the initiation of sexual activities with spouses, sexual desire and fantasies, spontaneous and nocturnal erections, and ejaculatory and orgasmic capacity.[8–10, 14, 15] Pubertal adolescent boys, compared with girls, demonstrate more rapid increases in sexual behaviors, a normal process that has been attributed at least in part to males' higher TTS levels.[16] Research both conducted and reviewed by Abel and associates[17] indicates that a large percentage of paraphilic behaviors begin in adolescence.

MPA has been postulated to influence endocrinologic mechanisms that affect androgen production, activity, and clearance, including TTS synthesis by the testes, TTS reductase activity in the liver, and displacement of TTS from sex steroid-producing protein.[3, 12] Recent research conducted on male cynomolgus monkeys suggests that MPA reduces TTS uptake into brain and pituitary gland cell nuclei that are associated with sexual behavior.[18, 19] Thus, MPA may act directly on brain mechanisms controlling sexual behavior. Michael and Zumpe[10] observed that MPA doses equivalent to clinically administered doses decreased the monkeys' ejaculations and mounting attempts even when plasma TTS levels were maintained in the upper range for intact males. These findings indicate that MPA's behavioral effects may be mediated by brain mechanisms regulating sexual motivation, relatively independent of reductions in circulating TTS levels.[19]

The role played by plasma TTS level monitoring during depo-MPA treatment for male sex offenders is not well defined. In particular, issues of dose-response, threshold levels, and end-organ sensitivity have not been worked out. Depo-MPA doses that suppress TTS plasma levels to less than 100 ng/dl, and preferably to less than 50 ng/dl, are recommended for treating the deviant behavior of male sex offenders. Generally, improvement in paraphilic behaviors parallel decrements in plasma TTS to castrate levels. But, while prepubescent/castrate levels may be necessary to suppress spermatogenesis, TTS decrements of this magnitude may not be required for inhibiting deviant sexual urges, drives, or behavior. Also, Meyer and associates[7] speculated that low plasma TTS concentrations may or may not indicate that intratesticular TTS concentration also is low.

Gottesman and Schubert[20] demonstrated that adult men with paraphilic behaviors could be treated successfully with low-dose oral MPA (60 mg/day; one subject received 80–100 mg/day). None of

their seven subjects had prior antiandrogen therapy. In the course of their open-label, nonblinded study, only two subjects achieved mean monthly serum TTS levels less than 300 ng/dl during 10 to 18 months of treatment; none were less than 150 ng/dl (normal, >300 ng/dl). The average percent decrease in TTS level was 59 percent (range = 45–75%). Outcome measurements were based on self-report of arousal experiences and functioning. Subjects described substantial relief from their paraphilic fantasies and preoccupations, none reported engaging in paraphilic behaviors while in treatment, and no significant MPA side effects were reported.

A related issue is whether this MPA-induced sexual drive reduction is global or whether it is selective for deviant impulses and behaviors. Can MPA be used to suppress deviant behaviors while the capacity to experience nondeviant sexual desires remains unimpaired? These questions relate to the usefulness of TTS levels as an indicator of likelihood for compliance with the therapeutic regimen and to patients' concerns regarding the quality of their sexual life. Those subjects of Gottesman and Schubert[20] who reported pretreatment (nondeviant) coital activity continued this activity during low-dose MPA treatment. However, these subjects reported a significant reduction in their number of spontaneous awakening morning erections and weekly ejaculations. These results suggest that differential reductions in nondeviant and deviant sexual drives and behaviors can be achieved with MPA therapy, at least with lower doses.

Another consideration is that circulating TTS levels may not be related to self-reports of sexual functioning. If this were true, then what purpose is served by monitoring these levels? Previously, we have shown that behavioral improvement is associated with concurrently reduced TTS levels.[21] Meyer and associates[13] found that pretreatment plasma TTS concentration was a predictor of reoffense even in patients receiving MPA and having TTS levels on treatment of less than 100 ng/dl. Shostakovich and associates[22] observed a significant lowering of TTS and high prolactin levels in individuals with heterosexual pedophilic disorders and with pedophilias without any aggressive and sadistic disorders. Thus, TTS levels may serve as a marker of subtypes of paraphilic behavior disorders or predictor of recidivism.

In this article, we describe the associations between pretreatment TTS levels and sociodemographic, clinical, and sexual behavioral characteristics. We also compare subjects with low and normal baseline TTS levels in terms of outcomes (deviant thoughts and activities, and recidivism) and time to return to pretreatment TTS after cessation of depo-MPA therapy. Our results will be considered as they relate to issues such as the effect of MPA on differential reductions in nondeviant and deviant sex drives and on specific subtypes of deviant behavior.

## Methods

***Subjects*** The 13 men who are the subject of this article were diagnosed with a paraphilic disorder and treated with i.m. depo-MPA. These subjects initiated treat-

ment with MPA in the Sexual Behaviors Clinic (SBC) in a large urban area, from 1986 through 1992, and are part of a larger series of studies of male sex offenders who have been evaluated and treated for paraphilic disorders in this SBC over the past decade.[21, 23–27] Patients selected for this sample have discontinued treatment and have had pretreatment and posttreatment TTS levels drawn (all but one subject had at least one TTS level drawn while on treatment).

This study was approved by the Human Investigation Committee (Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL) and written informed consent for open-label MPA treatment was obtained after a full explanation including a discussion of possible side effects. The consent sheet included the statement "[Y]ou do not have to accept this treatment as part of your probation or parole requirements, or as mandated by court order." Despite this wording, the authors acknowledge that some subjects were court-ordered for some treatment components at our facility. The Upjohn Company provided medication and covered the costs of the TTS levels.

***Procedure.*** *Evaluations* Evaluation for treatment, acceptance criteria, and the MPA treatment and monitoring protocols have been described elsewhere.[21] Briefly, all subjects underwent a comprehensive screening evaluation, including a psychiatric interview, psychological testing, and record review (psychiatric, medical, and legal), and corroborative interviews. The decision to offer MPA treatment included a consideration of diverse clinical elements, including intensity of sex drive and capacity for impulse control, denial, and lack of empathy.

TTS levels were monitored at approximately three-month intervals, during and following treatment, to ascertain whether they returned to pretreatment baseline levels. A self-rated psychosexual inventory surveying deviant and nondeviant sexual thoughts/fantasies, urges, erections, and masturbation to deviant and nondeviant stimuli, and engagement in deviant/nondeviant sexual activities was completed before, during, and after treatment to assess the presence of deviant and nondeviant sexual behaviors. Subjects were questioned regarding possible medication-related side effects and non-drug related medical problems during follow-up evaluations, and blood pressure and weight were monitored. Pretreatment penile plethysmography was performed to assess arousal to deviant sexual stimuli; these data have been presented.[28]

Recidivism was defined as either an arrest for a sexual offense committed subsequent to starting treatment or a self-report, made to a member of the treatment team, that he was reoffending.

*Treatment* All 13 subjects received i.m. depo-MPA injections weekly; none currently receives MPA. Treatment was initiated with 300 mg/week for five subjects, 400 mg/week for one subject, 600 mg/week for five subjects, 800 mg/week for one subject, and 900 mg/week for one subject. Eleven subjects remained in treatment for at least six months. The mean duration of MPA treatment was 96.2 $\pm$ 67.4 (1 SD) weeks (range, 4–218 weeks). Mean weekly doses averaged 348

± 127 mg (range, 158–600 mg/week), and total MPA exposure ranged from 2,400 to 110,900 mg. For those subjects on MPA treatment for at least six months, gradual dosage tapering was begun within the first 6 months for seven subjects and within 7 to 12 months for five subjects. Dose tapering was not begun for 17 months for the 11th subject. The most common reasons for terminating treatment were that probation ended (five subjects, 39%) and self-request while in remission (four subjects, 31%). Only one terminated primarily because of side effects and one because of finances.

Depo-MPA usually was stopped three to six months before the end of probation, so that recidivism could be monitored while they remained in the treatment program. The treatment program also included individual and group psychotherapy. All subjects participated in individual therapy and 10 of 13 subjects participated in group therapy, which focused on cognitive distortions, minimization, denial, lack of empathy, sex education, and self-awareness.

***Data Analyses*** Data were analyzed using SPSS for Windows (Release 6.0).[29] The sample was divided into normal (n = 9) and low (n = 4) TTS groups. Low pretreatment TTS level was defined as less than 300 ng/dl (ng%); this standard was established by the laboratory analyzing these blood samples. Kaplan-Meier survival curves[30] and the log-rank test[31] were used to compare time to return to baseline TTS levels for groups with pretreatment normal and low TTS. Categorical and non-normally distributed continuous data were analyzed with nonparametric tests; otherwise, parametric tests (e.g., multiple regression) were used. All statistical analyses were conducted as two-tailed tests unless otherwise specified. Statistical significance was set at $p \leq .05$, and trends also are indicated ($.05 \leq p \leq .1$).

## Results

***Pre-MPA Treatment—Study Sample.*** *Sociodemographic Characteristics* The 13 subjects who comprise this sample (Table 1) averaged 42.9 ± 17.0 years old (range, 24–77 years), and the racial/ethnic mix included 11 Caucasians and 2 Hispanics. Seven were single, two were married, and four were divorced or separated. Nine were employed at the time of their pretreatment evaluation. Educationally, all but two had at least a 4-year high school education; three had at least 16 years of formal education and only one had less than a grammar school education (third grade) (data were missing for 3 subjects). The Shipley Institute of Living Scale IQ estimate[32] was 101.9 ± 20.9 (range, 71–122; N = 8). There were no statistically significant differences between the two TTS groups for any of these variables.

*Clinical and Offense Characteristics* Nine subjects were on probation and were court-ordered for treatment (Table 2). Six subjects had previous arrests, four for sexual-related offenses. Eight subjects admitted to the current allegations, but once in treatment, 11 admitted to having a sexual behavior disorder. The primary deviant behavior involved child molestation for 10 (77%) of the sample; 4 of the 10 were primarily incestuous. Three subjects

**Table 1**
**Sociodemographic Characteristics of the 13 Subjects**

| Variable | Pretreatment Testosterone Level | |
|---|---|---|
| | ≥300 ng/dl (n = 9) | <300 ng/dl (n = 4) |
| Age, years | 42.6 ± 16.4 | 43.5 ± 21.1 |
| Race/ethnicity | | |
| Caucasian | 8 (89%) | 3 (75%) |
| Hispanic | 1 (11%) | 1 (25%) |
| Marital status | | |
| Married | 1 (11%) | 1 (25%) |
| Single | 5 (56%) | 2 (50%) |
| Divorced/separated | 3 (33%) | 1 (25%) |
| Employed | 6 (67%) | 3 (75%) |
| Education (highest level) | | |
| College degree | 3 (33%) | 1 (25%) |
| Some college | 1 (11%) | 0 |
| High school | 3 (33%) | 1 (25%) |
| <high school | 1 (11%) | 0 |
| (missing information) | 1 (11%) | 2 (50%) |
| Shipley IQ | 93.8 ± 24.0 (n = 4) | 110.0 ± 16.3 (n = 4) |

**Table 2**
**Offender and Victim Characteristics**

| Variable | Pretreatment Testosterone Level | |
|---|---|---|
| | ≥300 ng/dl (n = 9) | <300 ng/dl (n = 4) |
| Current status | | |
| Probation | 6 (67%) | 3 (75%) |
| Voluntary | 3 (33%) | 1 (25%) |
| Previous arrest(s) | | |
| ≥1 sexual offense | 2 (22%) | 2 (50%) |
| Nonsexual offense only | 2 (22%) | 0 |
| No arrest | 5 (56%) | 2 (50%) |
| Admit to allegation | 4 (44%) | 4 (100%) |
| Admit to paraphilic disorder | 7 (78%) | 4 (100%) |
| Multiple paraphilias | 4 (44%) | 2 (50%) |
| Primary paraphilic behavior | | |
| Child molestation, nonincest | 5 (56%) | 1 (25%) |
| Child molestation, incest | 3 (33%) | 1 (25%) |
| Exhibitionism (noncontact) | 1 (11%) | 2 (50%) |
| Median number of victims | 40 | 51 |
| Median age (years) of youngest victim | 10 | 9.5 |

primarily engaged in exhibitionism. Six subjects reported a history of multiple deviant sexual behaviors. The number of victims reported ranged from 1 to 200 (median = 40), and the median age of the youngest victim was 10 years (range, 4–16 years). The two TTS groups did not differ significantly on any of these variables.

The treating clinicians noted that only two subjects, both of whom were on probation (and both in the normal TTS group), were motivated for treatment at the beginning. One became less motivated during treatment and became the only recidivist (exhibitionism, his primary paraphilic disorder). Nine (all four low TTS and five normal TTS group) subjects were rated as motivated for treatment during the course of therapy. Ten subjects were judged to have a "good transference," seven (78%) in the normal TTS group and three (75%) in the low TTS group ($p$ = NS). Only 33 percent of the normal TTS group and 75 percent of the low TTS group had informants to provide corroborative information ($p$ = NS).

*Pretreatment TTS Levels* Pretreatment, nine subjects had normal TTS levels (414.3 ± 70.3 ng/dl; 345–540 ng/dl; normal range, 300–1200 ng/dl) and four had low TTS levels (262.8 ± 6.0 ng/dl; 255–268 ng/dl). The difference between the two groups was statistically significant (Mann-Whitney test, $Z = -2.78$, $p = .006$). Pretreatment TTS was not significantly correlated with age (Spearman rank correlation coefficient ($r_s$) = .14, $p < .65$).

***MPA Treatment and TTS Levels.*** *TTS Suppression* Eleven of the 13 subjects had TTS suppression to less than 100 ng/dl within 6.7 ± 4.6 weeks, and to less than 50 ng/dl within 10.6 ± 6.0 weeks. One subject in the normal TTS group suppressed only as low as 108 ng/dl, and another did not have a TTS level drawn before MPA was discontinued because of side effects.

*MPA Dose and TTS Levels* The low and normal TTS groups did not differ significantly in mean depo-MPA dose (normal TTS = 338.5 ± 131.0 mg/week, low TTS = 369.2 ± 135.2 mg/week). However, there was a trend for subjects with lower TTS levels to be treated for longer durations ($r_s = -.54$, $p = .055$). In comparing the groups, the low TTS group was treated for a significantly longer mean number of weeks (normal TTS = 71.9 ± 55.7 weeks, low TTS = 150.9 ± 64.2 weeks; Mann-Whitney test, $Z = -2.16$, $p = .03$, two-tailed) and had a greater total dose exposure to MPA (Mann-Whitney test, $Z = -2.01$, $p = .04$). Also, dosage tapering began later in the low (median = 7 months) compared with the normal (median = 5 months) TTS group.

***Post-MPA Treatment and TTS Levels.*** *Age and TTS Levels* The time for the TTS level to return to baseline was correlated positively with age ($r_s = .77$, $p = .002$). Also, age was correlated negatively but nonsignificantly with duration of MPA treatment ($r_s = -.46$, $p < .12$).

*Return to Pretreatment TTS* Kaplan-Meier survival curves were constructed to examine the time to return to pretreatment TTS levels, and return to baseline TTS

levels was measured in two ways. First, we monitored the time to the normal range (≥300 ng/dl). Second, since the low TTS group started out below this threshold, we compared the two groups on time to return to ≥85% of the pretreatment baseline.

Using the absolute criterion, the normal TTS group returned to the normal range within a median of 317 days, or about 10 months. This is probably an overestimate, because TTS levels were checked only about every three months on follow-up. Only one normal TTS subject did not return to criterion level, and he was one of the longest treated subjects (188 weeks); his last follow-up TTS level was 65 days posttreatment. Because none of the low TTS group subjects attained a posttreatment level as high as 300 ng/dl, all observations in this group were censored data.

Seven subjects in the normal TTS group returned to within 85 percent of their baseline level (median time = 439 days) and one subject in the low TTS group did so (time for return = 479 days). Three subjects in the low TTS group followed for 88 to 497 days and two subjects in the normal TTS group followed for 65 to 729 days did not return to within 85 percent of their baseline level. One of these normal TTS group subjects returned to the normal range, but only to within 75 to 82 percent of his baseline at 729 days posttreatment. These survival curves were not significantly different from one another (log rank test = .82, $df = 1$, $p = .37$).

*Multiple Predictors of Return to Pretreatment TTS* To attempt to untangle the complex relationship of age, pretreatment TTS level, mean weekly MPA dose, and number of weeks of MPA treatment with length of time to return to baseline TTS, a multiple regression equation was calculated, simultaneously entering the four predictors into the model. Together, the four variables significantly predicted time to TTS return ($F = 4.94$, $df = 4,8$, $p < .03$), explaining over 70 percent of the variance in this outcome ($R^2 = .71$). In examining the contribution of each of the four variables, age, after adjusting for the effect of other three variables, was found to be the most significant predictor of the relationship ($R^2$ change = .33; $t = 3.0$, $df = 8$, $p < .02$). Age accounted for 46 percent of the total variability in the time to return to pretreatment TTS levels.

***Self-reports—Psychosexual Inventory*** Pretreatment, 77 percent (10 of 13) subjects admitted to deviant sexual fantasies and/or behavior, including 89 percent (eight of nine) in the normal TTS group and 67 percent (two of three; data missing for one subject) in the low TTS group. During treatment, 67 percent (six of nine) normal TTS subjects and 50 percent (two of four) low TTS subjects reported nondeviant sexual fantasies and/or behavior. Only two subjects, both in the normal TTS group (missing data for one subject), admitted to deviant fantasies or behavior during treatment, and both continued to report deviant thoughts throughout the post-MPA follow-up. One of these subjects discontinued treatment when his parole ended and relapsed. The second subject continued to have deviant thoughts, but had volunteered for the program and continued in remission while under care-

ful monitoring. Seventy-eight percent (eight of nine) normal TTS subjects and 75 percent (three of four) low TTS subjects reported nondeviant sexual fantasies and/or behavior after discontinuing MPA. None of the differences between the two TTS groups was statistically significant.

## Discussion

In this study we examined the effect of depo-MPA on TTS levels and self-reported sexual activities for 13 treated male paraphilic patients. The data showed that subjects with low pretreatment TTS received MPA for longer periods of time, and older subjects took longer to return to pretreatment TTS levels, despite being treated for shorter periods of time. Median (and mean) weekly MPA doses did not significantly differ between the two groups. However, the results of the multiple regression analysis indicate that although subjects with lower TTS levels may be more sensitive to MPA's TTS-suppressive effects, this effect may be mediated by age. The two TTS groups, determined by pretreatment blood concentrations, could not be distinguished on the basis of their sociodemographic and clinical features, or by their self-reported nondeviant and deviant sexual fantasies and behaviors.

Establishing clinically meaningful TTS levels is important for guiding antiandrogen therapy during the hormonal treatment of male sex offenders. Pirke and associates[33] observed that a lower TTS level threshold of 200 to 450 ng/dl is necessary for maintaining sexual functioning. Recent findings by Gottesman and Schubert[20] challenge the recommendation that adequate MPA suppression requires that sex offenders' TTS levels should be less than 100 ng/dl. They observed that low-dose oral MPA, producing TTS levels not lower than 150 ng/dl, were sufficient to suppress deviant sexual behaviors, yet permit nondeviant sexual activity. However, their subjects' behavioral self-reports were not corroborated by informants, and endocrinologic mechanisms relating to partial reduction in TTS levels and consequent behavioral implications were not discussed. Also, they studied only seven subjects.

In comparison, despite our subjects' low TTS levels during treatment, they reported a differential effect of MPA on deviant and nondeviant sexual fantasies and behaviors. Specifically, more than half still experienced nondeviant sexual behaviors. However, because we too used self-report measures, it is conceivable that *neither* deviant nor nondeviant behaviors were suppressed fully. But, from all available information, including that gleaned from informants in about half of the cases and from group therapy reports, their self-disclosures seemed to be accurate. Recidivism occurred in only one subject, an exhibitionist who had normal pretreatment and posttreatment TTS levels.

Further, MPA treatment generally was safe. Only one subject discontinued treatment because of side effects; he had normal pretreatment and posttreatment TTS levels.

Thus, we could not replicate Shostakovich and associates'[22] or Meyer and associates'[13] findings that TTS levels may predict subtypes of paraphilias or out-

come. However, this was a small sample with variable follow-up intervals, the longest being six years after MPA treatment was terminated. Long-term follow-up extending at least a decade, monitoring both treated and untreated offenders, is necessary to assess efficacy and to detect recidivism due to the extremely low rate of self-reported sex offenses and the lifelong potential for reoffense.[34–36] Therefore, further studies with larger samples are required to better understand the role of TTS monitoring preceding as well as during and after MPA treatment, in order to justify its continued use as a measurement of treatment adequacy and to study its potential role as a predictor of treatment outcome.

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