The Relationships Between Serum Testosterone and Prolactin Levels and Nocturnal Penile Tumescence (NPT) in Impotent Men

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Serum testosterone (T) and prolactin (PRL) levels, nocturnal penile tumescence (NPT), penile and brachial blood pressure, and bulbocavernosus reflex latency (BCR) were assessed in 172 impotent men ranging in age between 19 and 60 years. Patients were also examined for Peyronie's disease. Patients who were taking drugs that are known to affect T or PRL levels, and those with overt primary or secondary testicular failure, liver disease or renal disease, were excluded from the study.

Androgen deficiency (T < 264 ng/dl) or hyperprolactinemia (PRL > 15 ng/ml) was observed in 22% of the patients, and 62% had abnormal NPT. We found that NPT was abnormal in 11 of the 12 men (91.7%) with T levels below 251 ng/dl or with PRL levels above 25 ng/ml (P < .001), and in 81.0% to 93.8% of men with other detectable and relevant medical abnormalities. Eight of the 12 patients with T levels below 251 ng/dl or PRL levels above 25 ng/ml had other detectable abnormalities. In contrast, NPT was abnormal in only 10 of 34 men (29.4%) who had no apparent medical abnormality or disease.

These studies indicate that in impotent men, T deficiency and/or hyperprolactinemia, alone or with other conditions, are associated with abnormal NPT sufficiently frequently to warrant routine measurement of both T and PRL, particularly if it can be demonstrated that correction of these abnormalities restores potency.

Key words: impotence, serum testosterone, serum prolactin, nocturnal penile tumescence, hyperprolactinemia, androgen deficiency.

Several investigators have suggested that serum levels of prolactin (PRL) and testosterone should

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be measured routinely in men presenting with impotence (Spark et al, 1980; Pont et al, 1979; Franks et al, 1977). A variety of factors have led to this recommendation. First, impotence is a well recognized symptom in patients with severe primary testicular disease (Spark et al, 1980), and may be a presenting symptom in up to 76% of men with tumors in the region of the sella turcica. In the latter group of patients it may be associated with androgen deficiency and/or hyperprolactinemia (Lundberg and Wide, 1978). These authors observed that 35 of 40 men (88%) with tumors in the region of the sella turcica had subnormal serum concentrations of testosterone, and 15 of 36 (39%) patients had serum levels of PRL that exceeded 15 ng/ml. The latter finding is of particular interest since some evidence suggests that hyperprolactinemia per se may be causally related to impotence (Thorner and Besser, 1978; Carter et al, 1978). Second, effective therapy is available for many patients with androgen deficiency or hyperprolactinemia. It is now possible in some cases to remove a small tumor surgically and to preserve normal anterior pituitary function (Pont et al, 1979). In those situations where hyperprolactinemia persists, administration of the long acting dopamine agonist, bromocriptine, may normalize both PRL and testosterone levels and restore sexual function and spermatogenesis (Thorner and Besser, 1978; Carter et al, 1978; Segal et al, 1979). When androgen deficiency results

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from either primary testicular failure or hypopituitarism, it may be corrected by the administration of exogenous androgens, and an increase in sexual function usually follows (Spark et al, 1980; Davidson et al, 1979). In those situations where gonadotropins are deficient and fertility is also a consideration, therapy with gonadotropins may restore both potency and fertility (Paulsen, 1968).

Although serum levels of testosterone and PRL may be critical etiological factors in some impotent patients, reports estimating that impotence has a psychological basis in 90% of patients (Strauss, 1950; Cooper, 1950) suggest that endocrine causes of impotence may be rare and that routine measurement of serum levels of testosterone and PRL may not be justified. To examine these questions, we studied a large sample of impotent men who were referred to the Baylor Sleep Laboratory for measurement of nocturnal penile tumescence (NPT) in order to differentiate organic from psychogenic impotence (Karacan et al, 1978). A primary objective of this study was to assess the relationship between NPT and serum levels of testosterone and PRL.

Materials and Methods

Subjects were selected from patients referred to the Baylor Sleep Disorders Center between July, 1977 and March, 1980 for evaluation of impotence. A psychiatric interview was conducted and a detailed medical and sexual history was obtained for each patient. In addition, a physical examination was performed, including measurement of penile and brachial systolic blood pressures, bulbocavernosus reflex latency (BCR) for neuropathy, and penile examination for Peyronie's disease.

Subjects who were known to have pituitary tumors, isolated gonadotropin deficiency, primary testicular failure, severe liver or renal disease, or gross psychopathology, and those who were taking drugs known to affect PRL secretion (reserpine, methyldopa, phenothiazides, amitriptyline, imipramine, levodopa, bromocriptine) were excluded from this study (Horowitz and Goble, 1979). Similarly, men taking drugs known to affect serum levels of testosterone or its action on target organs (spironolactone, cimetidine, and androgens) were excluded. Furthermore, the study was limited to men who were between 19 and 60 years of age, since total and free testosterone levels are more commonly abnormal after age 60 (Pirke and Doerr, 1975; Stearns et al, 1974). Blood samples for measuring PRL and testosterone concentrations were obtained on the first evaluation in the sleep laboratory. Three specimens were obtained at 10 minute intervals between 6:30 and 7:30 AM, after the patients were awake. Mean levels were computed to minimize variability due to episodic secretion (Goldzieher et al, 1976); however, technical difficulties resulted in 13% of the patients having only two testosterone values and 11% having only two PRL determinations.

Serum concentrations of PRL (Hwang et al, 1971) and testosterone (Nieschlag and Loriaux, 1972) were determined by radioimmunoassay in the Baylor Central Endocrine Laboratory. The interassay coefficients of variation for our medium pools was 8% for PRL and 10% for testosterone. The ranges of values in our laboratory for a single specimen obtained between 7:00 and 9:00 AM from 24 fertile and potent men, 20 through 40 years of age, were 1 to 15 ng/ml for PRL and 264 to 1005 ng/dl for testosterone. The mean values obtained from patients in this study were compared with our normal range.

Each subject was monitored polysomnographically in the sleep laboratory for three consecutive nights using standard procedures for electroencephalogram (EEG), electromyogram (EMG), and electrooculogram (EOG) activity in order to determine the occurrence of NPT during non-rapid eye movement sleep (non-REM) and to assure that abnormal NPT was not simply a result of disturbed sleep. Detection of NPT was accomplished with mercury-filled capillary strain gauges in accordance with previously described procedures (Karacan et al, 1978). All nocturnal recordings and changes in penile tumescence were scored without knowledge of the endocrine results.

Episodes of REM-related tumescence were evaluated according to criteria which have been derived from studies in over 500 complaining and noncomplaining men in all age groups (Karacan, 1981). Subjects were awakened during a typical episode on the first and third nights of the evaluation; estimates of the degree of erection were obtained from both the patient and technician, and rigidity measurements were made. A buckling force of greater than 450 g was considered to be of adequate rigidity for vaginal penetration. In most noncomplaining men, however, buckling usually occurs at greater than 1000 g of force. The criterion for adequate duration of maximum tumescence was at least one minute, but again in normal subjects the duration of maximum tumescence is around 10 minutes. Both criteria-duration and rigidity-are essential to consider before making the determination of whether the erection is sufficient for penetration. If penile buckling occurred at less than 450 g pressure, the erection was considered to be abnormal. This measurement is useful since some patients may have a normal increase in circumference during NPT, but insufficient rigidity for vaginal penetration.

In this study, the limits used to compare endocrine parameters with NPT were somewhat beyond their normal ranges: for testosterone, less than 251 ng/dl; for PRL, greater than 25 ng/ml. We did not use an upper limit for testosterone or a lower limit for PRL. Penile systolic blood pressure was considered abnormal if it was less than 80% of brachial pressure, and BCR was considered abnormal if the latency value was greater than 40 msec (Ertekin and Reel, 1979).

Chi-square tests were used to investigate possible as-

Clinical Findings*	Number of Patients	Percent of Patients with Abnormal NPT	Significancet
Delayed Bulbocavernosus Reflex	16	93.8	P < 0.001
Peyronie's Disease	14	92.9	P < 0.001
Testosterone < 251 ng/dl or			
Prolactin > 25 ng/ml	12	91.7	P < 0.001
Low Penile Blood Pressure	63	81.0	P < 0.001
Otherst	40	52.5	P < 0.10
No Apparent Medical Abnormality	34	29.4	

TABLE 1. Percent of Patients with Abnormal Nocturnal Penile Tumescence (NPT) Classified by Medical Abnormality

* Patients may be included in one or more of the first four categories; the "others" were exclusive of the first four categories. + Compared with group with no medical abnormality.

‡ Includes patients with a history of relevant medical conditions. The percent of patients with abnormal NPT is in parentheses: 15 with hypertension (33%); four with hypertension and diabetes (100%); 10 with diabetes (80%); five with back or pelvic trauma (80%); four with multiple sclerosis (0%); one hemiplegic (0%); one with peripheral nerve injury (0%).

sociations between NPT and endocrine or other medical abnormalities. The effect of age on the relationship between NPT and testosterone level and NPT and PRL level was evaluated by means of analysis of variance. For this analysis the patients were divided into two subgroups by age (19 to 39 and 40 to 60); NPT was classified as described above, and the mean values of testosterone and PRL in the resulting groups were compared. Pairwise t-test analyses were made with respect to the effect of age in each NPT category.

Results

One hundred seventy-two of the patients evaluated in the Baylor Sleep Disorders Center between July, 1977 and March, 1980 fulfilled the criteria for inclusion in this study. Twenty-two percent of these men had laboratory evidence of androgen deficiency (testosterone levels below 264 ng/dl) or hyperprolactinemia (PRL concentrations in excess of 15 ng/ml), and NPT was found to be abnormal in 62% of the patients.

Abnormal NPT occurred in 11 of the 12 men with abnormal levels of testosterone (<251 ng/dl) or PRL (>25 ng/ml) (Table 1). In addition, the percentage of patients with abnormal NPT was significantly higher among those with delayed BCR, Peyronie's disease, or low penile blood pressure than among 34 patients who had no evidence of relevant medical abnormality or disease. Many of the patients had more than one abnormality. The 12 patients with testosterone concentrations below 251 ng/dl or PRL levels in excess of 25 ng/ml included one subject with low penile blood pressure and hypertension, one with low penile blood pressure and diabetes, one with hypertension and diabetes, one with hypertension, two with diabetes, one with Peyronie's disease and abnormal BCR, and one with a history of pelvic fractures. Only four patients had an isolated abnormality of serum testosterone levels or serum PRL levels, as defined by this study.

The distribution of serum PRL and testosterone values, in relation to NPT, is illustrated in Fig. 1. Note that all six patients with testosterone values below 251 ng/dl had abnormal NPT, as did five of the six patients with PRL values in excess of 25 ng/ml. No relationship between serum testosterone and PRL levels was discernible in this large group of impotent men. The same was true when only the subjects with PRL levels above 15 ng/ml and testosterone values below 264 ng/dl. Four men had PRL levels above 15 ng/ml and testosterone values that exceeded 1005 ng/dl.

The interrelationships among age, NPT, and mean serum testosterone and PRL levels were also examined. For this analysis, individuals with normal tumescence were compared with those who had abnormal tumescence (Table 2). Serum testosterone levels were significantly greater in the group of 19 to 39-year-old men than in the group of 40 to 60-year-old men. Mean values of testosterone were not significantly associated with NPT within any age group. Similar analysis of PRL values failed to demonstrate a significant relationship with age or NPT.

Discussion

Twenty-two percent of the impotent men in this study had serum concentrations of testosterone below the lower limit or PRL values above the upper limit of their respective normal ranges, and



Fig. 1. The distribution of serum PRL and testosterone values in relation to nocturnal penile tumescence in 172 impotent men. Each point represents the mean serum testosterone and prolactin levels for one man. The dashed lines indicate the lower limit of normal range for testosterone levels (251 ng/dl) and the upper limit of normal range for prolactin values (25 ng/ml) which were used in the analysis of this data. Normal NPT is plotted with a (.) and abnormal NPT with an (X).

62% had abnormal NPT. Although the percentage of endocrine values outside the normal range is high in this group of patients, it is below the value of 32% reported by Ambrosi et al (1977) who examined 47 patients. The high frequency of abnormal NPT in this impotent population indicates the presence of an organic etiology (ies) in the majority of those studied.

Five percent of the patients had mean serum

TABLE 2. The Relationship of Age, Nocturnal Penile
Tumescence (NPT), and Serum Testosterone in
Impotent Men

NPT	Age	Number of Patients	Serum Testosterone (ng/dl)*
Abnormal	19-39	19	720.6 ± 66.5
	40-60	87	560.0 ± 25.0+
Normal	19-39	21	767.4 ± 56.8
	40-60	45	553.7 ± 36.9±

* Mean \pm SEM; $\pm P < 0.05$; $\pm P < 0.01$.

testosterone levels below 264 ng/dl. While several investigators have recognized that values as low as this may occur in normal males (Smith et al, 1974; Paulsen, 1974), other studies of impotent men have considered values of less than 350 to 400 ng/dl as subnormal (Spark et al, 1980; Ambrosi et al, 1977). We deliberately excluded patients taking drugs known to affect serum testosterone levels or androgen action. Furthermore, conditions such as renal failure or significant liver pathology, which can be diagnosed by clinical examination and/or routine chemistries, were excluded. No patients with other symptoms of pituitary disease were included; and blood specimens were obtained in the AM when mean levels tend to be maximal. Thus, the 5% prevalence probably represents the minimal number of impotent men with androgen deficiency in this type of population. The explanation for the low testosterone values in these patients is not immediately apparent, but the presence of primary pituitary or testicular disease must be considered.

Attempts to correlate testosterone levels with impotence have been complicated by limited objective criteria, multiple etiologies of impotence, episodic secretion of testosterone, differences in free testosterone levels due to variability in the transport protein (TeBG), and individual variability (Schiavi and White, 1976; Nieschlag, 1970). Additionally, serum concentrations of estradiol and the activity of sex steroids in target tissues are important factors. Since other investigators have observed a reduction in total testosterone levels with aging (Pirke and Doerr, 1975; Stearns et al, 1974), the age range was restricted to 19 to 60 years. Even within this age range, testosterone levels were significantly lower in the 40 to 60 age group than in the younger group. However, there was no correlation of testosterone levels with NPT. While it is not yet possible to accurately assess all of the recognized variables, Raboch and Starka (1973) observed impotence to be associated with testosterone levels lower than 300 ng/dl. Using quantitative techniques to assess subjective parameters, Davidson et al (1979) reported that testosterone treatment of six men with serum values less than 150 ng/dl resulted in an increase in total erections, nocturnal erections, and coital frequency. These observations are consistent with our clinical experience. The mechanism(s) by which testosterone affects potency is not known; however, most investigators feel that androgens have a direct effect on the central nervous system. When nocturnal erections were monitored in the present study, they were normal in one patient who had a mean testosterone level of 259 ng/dl and abnormal in the six men with mean values less than 251 ng/dl. A subnormal value of testosterone does not exclude the possibility of other causes of impotence or of abnormal NPT; four of these six men had one or more other conditions that could have been a primary or contributing cause of abnormal NPT; namely, low penile blood pressure, systemic hypertension, or a history of diabetes. Two patients with hypertension were being treated with Minipress (prazosin hydrochloride, Pfizer), Hygroton (Chlorthalidone, USV Pharmaceutical), or Inderal (propranolol hydrochloride, Averst). Use of each of these drugs has been associated with impotence only in rare cases. A third was taking Exidrix (hydrochlorothiazide, Ciba). We are currently using men with severe

androgen deficiency for the study of effects of testosterone replacement on NPT and rigidity of erection.

We were surprised to find that 7% of the impotent men in the present study had mean testosterone values that exceeded the upper limit of our normal range. There may be several explanations for this observation. First, sampling was conducted early in the morning when testosterone levels tend to be maximal (Faiman and Winter, 1971; de Lacerda et al, 1973). Second, although variability of the assay could be responsible for these high levels of testosterone, patients were randomly distributed throughout the study and 11 of these 12 patients had at least two determinations that exceeded the normal range. Third, these men could have an increased concentration of testosterone-estrogen binding globulin (TeBG) as seen in hyperthyroidism and some other conditions, and thus the concentration of free testosterone could be normal. Fourth, patients could have taken exogenous androgens without disclosing this to us. Last, there could be partial resistance to androgen action in target tissues (Griffin and Wilson, 1980). Since only eight of 12 patients with elevated testosterone had abnormal NPT, high testosterone values were not correlated with this parameter; however, further studies may be indicated to explore the finding of hyperandrogenism in impotent males.

Concentration of PRL above the normal range was the most frequent endocrine abnormality observed. The 18.6% incidence of hyperprolactinemia in this study is similar to the incidence of 17% in the report by Ambrosi et al (1977). Some of the abnormally high values in our patients may have been due to the time of sampling. It is known that highest levels of PRL are normally attained between 5 and 7 AM (Sassin et al, 1972; Nokin et al, 1972). Moreover, although patients using drugs known to enhance serum levels of PRL were excluded, the existence of hypothyroidism, which may cause hyperprolactinemia, was not excluded in all patients. Although most of our patients had only minor elevations and no patient had PRL values that exceeded 50 ng/ml, PRL-secreting pituitary tumors cannot be excluded on the basis of available data.

Several studies have associated hyperprolactinemia with impotence (Thorner and Besser, 1978; Carter et al, 1978). It is of interest to note that five of the six men with PRL levels in excess of 25 ng/ml had abnormal NPT. If there is a causal relationship between impotence or abnormal NPT and hyperprolactinemia, the mechanisms are as yet poorly defined. Elevated PRL levels could have a direct effect on the central nervous system or an indirect effect on potency by impairing testosterone secretion. Four of the six men with PRL concentrations in excess of 25 ng/ml had one or more other conditions that could have contributed to an abnormal NPT namely, Peyronie's disease, hypertension, delayed BCR, a history of diabetes, or a history of pelvic fractures.

The relationship between PRL and testosterone levels is complex and controversial. It has been suggested that serum testosterone levels are both positively (Rubin et al, 1976) and negatively (Thorner and Besser, 1978; Carter et al, 1978; Faglia et al, 1977) correlated with the serum concentrations of PRL. In the present studies, we found no relationship when the total sample was examined or when only patients with PRL levels greater than 15 ng/ml were assessed. Only two of our patients had elevated PRL levels and subnormal testosterone values.

Normalization of PRL levels by the use of bromocriptine and/or selective removal of a prolactinoma has been reported to restore potency (Pont et al, 1979; Thorner and Besser, 1978; Carter et al, 1978). This has been most effective in patients who have small pituitary tumors and in patients with PRL levels exceeding 100 ng/ml. However, when impotent patients with PRL levels equal to or smaller than 22 ng/ml were treated with bromocriptine in a carefully controlled study, no significant improvement was observed (Ambrosi et al, 1977). It may be that the impotence in some of these patients was due to other factors, but it seems likely that bromocriptine treatment may not benefit patients with normal testosterone levels and minimally elevated PRL concentrations (<25 ng/ml).

We found a significantly higher incidence of abnormal NPT, not only in patients with exceptionally low testosterone or high PRL values, but also in impotent patients with other conditions including delayed BCR, Peyronie's disease, low penile blood pressure, hypertension, and other medical problems. From this data it is not possible to attribute diminished NPT to any specific abnormality or abnormalities, because these patients generally had multiple conditions. It seems clear, however, that there is a connection between changes in NPT and some underlying pathologies related to the abnormalities observed. There were ten patients who had abnormal NPT but no other measured abnormality. This could possibly be attributed to conditions such as autonomic nervous system abnormalities that were not evaluated. Also, some of these patients had borderline values of the parameters that were evaluated. These borderline values may be indicative of processes that are degenerating to a pathological state.

In summary, 38 of 172 impotent men (22%) had mean testosterone levels less than 264 ng/dl and/or PRL levels greater than 15 ng/ml. All but one of 12 men with testosterone values below 251 ng/dl or PRL values in excess of 25 ng/ml had abnormal NPT. If objective measurements demonstrate that correction of these abnormalities restores potency, we believe that routine measurement of testosterone and PRL is indicated in the evaluation of impotent men.

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