Journal of Andrology, Vol. 10, No. 6, November/December, 1989

Quantitative Assessment of Nocturnal Penile Tumescence and Rigidity In Normal Men Using a Home Monitor

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Current methods now permit the measurement of nocturnal penile tumescence and rigidity (NPTR) in men with erectile dysfunction. But the relationship of rigidity to tumescence and the changes in rigidity with age have not been defined in nornal men. Accordingly, the authors assessed NPTR in 47 normal men using a portable, take-home monitor (Rigiscan). Penile tumescence time was found to decrease with advancing age ($p < 0.05$), whereas the number of erectile episodes and penile rigidity did not significantly change with age for men in the third through sixth decades ($p < 0.05$). Using area-under-the-curve as an integrated measure of amplitude and duration, significant correlations between tumescence and rigidity ($p < 0.001$), and between tip and base measurements ($p < 0.001$) were found. With these normative data, prospective studies should determine the sensitivity and specificity of various NPTR parameters in the diagnosis of erectile dysfunction.

Key words:Nocturnal penile tumescence, erectile dysfunction, rigidity.

J Androl 1989; 10:492-497.

Nocturnal penile tumescence (NPT) monitoring provides a measure of the physical integrity of the erectile mechanism (Marshall et al, 1982). Techniques for monitoring NPT have been limited to the measurement of penile tumescence, whereas, penile rigidity has been quantified only by measuring penile buckling force (Karacan and Moore, 1986). A recently developed NPT instrument (Rigiscan: Dacomed Corp. Minneapolis, MN) now provides simultaneous, continuous measurement of both tumescence and rigidity (Bradley et al, 1985). Normative values for penile rigidity, however, have not been established. Accordingly, this study assessed nocturnal penile tumescence and rigidity (NPTR) in normal men of various ages using the Rigiscan instrument in order to define the changes in NPTR with age, to determine the relationship between rigidity and tumescence, and to delineate normal values for NPTR parameters. This study sought to establish normative data for future studies of men with erectile dysfunction.

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Received for publication June 19, 1989; accepted for publication July 17, 1989.

Materials and Methods

Subject Selection

Forty-seven men between the ages of 21 and 75 yr (mean ± standard deviation [SD], 40.6 ± 13.3) participated in the study. The subjects were healthy volunteers recruited from the NIH campus and surrounding community. All subjects were free of medications at the time of study. Participants had normal sexual function by history (libido, potency), a normal sleep history, and a normal physical examination including measurement of testicular volume. Screening laboratory data (biochemical profile, complete blood count, urinalysis, and thyroid function tests) and serum concentrations of testosterone, sex hormone binding globulin, LH, FSH and prolactin were within the range of normal for our laboratory (data not shown). The study protocol was approved by the National Institutes of Health Institutional Review Board, and informed consent was obtained from each subject prior to starting the study.

NPTR Instrument and Technique

The Rigiscan NPTR instrument is a portable unit worn on the subject's thigh in a cloth pouch. The instrument can be used at home or in a hospital, but does not require a sleep laboratory. Connected to the instrument via flexible cables are two soft loops, which are applied to the tip and the base of the penis. The loops gently contract at intervals of 15 seconds, applying pressure to the penile shaft with each contraction. Tumescence (penile circumference) is measured during each loop contraction every 15 sec and rigidity (penile hardness) is measured during alternate contractions every 30 sec. Tumescence is expressed in cm (range: 5–15 cm), and rigidity in percent relative to a standard hard-rubber cylinder (range: 0–100% of standard). Measurements obtained during three sleep sessions (maximum 10 h per session) are stored in internal memory and are later downloaded into a microcomputer for processing. The processed data, including a data summary table, are stored on disk and can be displayed and printed graphically (Fig. 1). The NPTR instrument is initially calibrated by the manufacturer, and can be checked for accuracy with a foam cylinder of known circumference and hardness. Further details concerning instrument design and technique have been published (Bradley et al, 1985). At the time of the initial clinic visit, subjects were instructed in the use of the NPTR instrument. Subjects were told to place the loops on their penis and turn the instrument on immediately before retiring, and to turn the instrument off upon awakening. Subjects were requested to use the instrument at home for three nights (sessions) and to abstain from drugs, alcohol, and caffeine-containing beverages in the evening prior to each session. Subjects were also told to refrain from sexual activity while using the instrument.

NPTR Analysis

The NPTR data processing program yields a number of NPTR parameters from each session: (1) sleep time (ST), the length of time that the instrument was on; (2) minimum and maximum tumescence, measured at the tip and base; and (3) maximum rigidity, tip and base. Delta-tumescence (δtum; [maximum-minimum tumescence] in cm) and the fractional change in tumescence (δtum/[maximum tumescence-δtum]) were calculated for both tip and base.

The number of erectile episodes and total tumescence time were measured manually from a printed, graphic display of each session. In the absence of any standardized criteria in the literature, an erectile episode was defined as a 0.75 cm increase in base tumescence (over baseline) that was sustained for at least 10 min (0.167 h); this empirical definition is in keeping with the instrument's design (Bradley et al, 1985). Total tumescence time (TTT) was defined as the total duration of all erectile episodes at the base. Using these parameters, this study calculated the ratio of tumescence time to sleep time (TTT/ST), the number of episodes per hour of sleep ([# of episodes]/

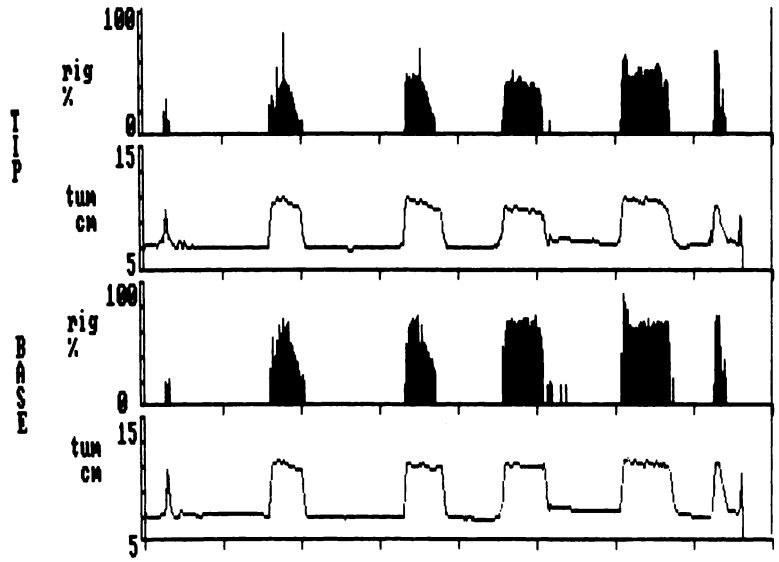

Fig. 1. Representative NPTR session from a 41-year-old male. Penile rigidity (in % of standard) at the tip and base are shown in the first (top) and third panels, respectively. Penile tumescence (in cm) at the tip and base are shown in the second and fourth (lower) panels. Time is plotted on the abscissa in 1 hour intervals.

TABLE 1. Mean (± SEM) NPTR Parameters in Normal Men by Decade

Age (Year)	Sleep Time (hour)	Episodes per Session (number)	Total Tumescence Time (hour)†	Tumescence Time per hour of sleep†	Episodes per hour of sleep (no./hour)	Tumescence time per episode† (hour)	Δ–Tumescence (cm)		Fractional Δ–Tumescence	
							tip*	base	tip*	base
20–29 (n = 11)	6.26 ± 0.16	3.7 ± 0.2	2.50 ± 0.15	0.40 ± 0.03	0.60 ± 0.04	0.68 ± 0.04	5.0 ± 0.2	4.9 ± 0.2	0.78 ± 0.04	0.69 ± 0.03
30–39 (n = 12)	6.55 ± 0.34	4.0 ± 0.3	2.54 ± 0.24	0.38 ± 0.03	0.61 ± 0.03	0.65 ± 0.05	5.2 ± 0.3	5.0 ± 0.3	0.82 ± 0.05	0.71 ± 0.04
40–49 (n = 10)	6.11 ± 0.27	4.2 ± 0.4	2.06 ± 0.23	0.33 ± 0.03	0.68 ± 0.04	0.49 ± 0.03	4.2 ± 0.2	5.3 ± 0.2	0.66 ± 0.03	0.75 ± 0.04
50–59 (n = 10)	6.68 ± 0.40	3.5 ± 0.3	1.60 ± 0.19	0.25 ± 0.03	0.53 ± 0.05	0.50 ± 0.07	4.2 ± 0.3	4.7 ± 0.1	0.69 ± 0.06	0.69 ± 0.02
60–69 (n = 2)	7.31 ± 0.22	3.2 ± 0.5	1.25 ± 0.20	0.17 ± 0.02	0.44 ± 0.5	0.41 ± 0.01	4.8 ± 0.2	5.2 ± 0.2	0.73 ± 0.05	0.69 ± 0.08
≥ 70 (n = 2)	7.34 ± 0.11	2.7 ± 1.0	0.79 ± 0.34	0.11 ± 0.05	0.36 ± 0.14	0.28 ± 0.01	3.9 ± 0.2	5.1 ± 0.8	0.61 ± 0.02	0.71 ± 0.15
All subjects (n = 47)	6.48 ± 0.14	3.8 ± 0.1	2.10 ± 0.12	0.33 ± 0.02	0.59 ± 0.02	0.56 ± 0.03	4.7 ± 0.1	5.0 ± 0.1	0.74 ± 0.02	0.71 ± 0.02
Intersubject variance / Intrasubject variance	0.82	0.67	1.63	2.50	0.88	0.65	0.78	1.49	0.45	1.50

*P < 0.05 versus age.
†P < 0.001 versus age.
Numbers in parentheses indicate the number of subjects in each group.

ST), and the average tumescence time per episode (TTT/[# of episodes]).

In order to incorporate both amplitude and duration in a single measure we computed area-under-the-curve values (AUC) for tumescence and rigidity (tip and base). AUC was derived by computer and expressed as cm/h for tumescence or (% standard) h for rigidity. This method approximates the area under a curve by calculating the area of a series of rectangles:

$$AUC = t \Sigma T_n$$

where T_n is each tumescence (or rigidity) data point, and t equals 0.0042 h (15 sec) for tumescence (or 0.0084 h [30 sec] for rigidity). Only those tumescence or rigidity data points that fell within erectile episodes, as previously defined, were used in the calculation of AUC. Furthermore, each tumescence data point was expressed as the change from baseline (average minimum tumescence) rather than the absolute tumescence value to minimize differences in flaccid penile size.

Statistical Methods

The data are shown as mean ± standard error of the mean (SEM). A fixed-effects model analysis of variance (ANOVA) was used to compare the three recorded sessions, whereas a random-effects model ANOVA was used to determine within-subject and between-subject variability (Snedecor and Cochran, 1980). Relationships between NPTR parameters were tested by Spearman's rank correlation (Snedecor and Cochran, 1980). The Shapiro-Wilk test for normality was used to determine the distribution characteristics of each parameter (Shapiro and Wilk, 1965). If a parameter fit a normal distribution curve, then the lower fifth percentile was estimated using normal distribution theory. If a parameter was not normally distributed, then the lower fifth percentile was derived by linear extrapolation from the empirical distribution function (Fisher, 1969). A p value < 0.05 was considered statistically significant.

Results

Variability of NPTR Measures

All subjects used the Rigiscan instrument for at least two nights, and 44 of 47 subjects (94%) completed three sessions. Contrary to initial expectations, there were no statistically significant differences between the three sessions for all NPTR parameters ($p < 0.05$). Accordingly, the data for each subject were combined from all recorded sessions to yield a mean for each parameter for that individual.

The between-subject and within-subject (replicate error) variability was expressed as a ratio of variances for each NPTR parameter (Tables 1 and 2, bottom row). Between-subject variability was greater than within-subject variability (ratio > 1.0) for total tumescence time (TTT), tumescence time per h (TT/

TABLE 2. Mean (± SEM) NPTR Parameters in Normal Men by Decade

Age Year	Maximum tumescence (cm)		Maximum rigidity (% standard)		Area-under-the-curve Tumescence (cm. hour)		Area-under-the-curve Rigidity (% of Standard hour)	
	tip†	base	tip	base	tip†	base*	tip	base
20–29 (n = 11)	11.4 ± 0.2	12.0 ± 0.3	77.6 ± 3.5	76.7 ± 3.2	82.2 ± 10.3	101.7 ± 11.1	65.8 ± 14.9	75.0 ± 7.2
30–39 (n = 12)	11.5 ± 0.3	12.1 ± 0.3	76.9 ± 3.3	80.2 ± 2.2	87.9 ± 11.0	101.1 ± 12.6	57.7 ± 8.8	67.9 ± 9.3
40–49 (n = 10)	10.7 ± 0.3	12.3 ± 0.2	79.7 ± 2.9	85.4 ± 2.4	71.3 ± 8.6	112.7 ± 11.6	55.9 ± 8.5	86.0 ± 12.8
50–59 (n = 10)	10.4 ± 0.4	11.8 ± 0.2	82.2 ± 4.6	84.1 ± 2.1	52.0 ± 10.1	67.5 ± 7.2	53.3 ± 10.9	66.2 ± 7.5
60–69 (n = 2)	11.5 ± 0.0	12.7 ± 0.4	67.5 ± 9.5	72.7 ± 0.0	57.7 ± 28.7	72.3 ± 30.0	28.8 ± 20.2	38.5 ± 11.2
≥ 70 (n = 2)	10.3 ± 0.4	12.3 ± 0.4	47.3 ± 2.7	61.2 ± 14.5	22.8 ± 9.0	34.4 ± 16.8	9.5 ± 6.4	21.2 ± 15.5
All Subjects (n = 47)	11.0 ± 02	12.1 ± 0.1	77.1 ± 1.9	80.1 ± 1.5	71.4 ± 5.2	92.5 ± 5.8	55.0 ± 5.2	69.8 ± 4.7
Intersubject variance / Intrasubject variance	1.39	3.02	1.89	0.99	1.25	1.84	1.00	1.30

*P < 0.05 versus age.
†P < 0.01 versus age.
Numbers in parentheses indicate the number of subjects in each group.

h), maximum tumescence and rigidity, and AUC (tumescence and rigidity). In contrast, between-subject variability was less than within-subject variability (ratio < 1.0) for sleep time, the number of erectile episodes, and tumescence time per episode (TT/epi). For delta-tumescence (absolute and fractional δtum), the between-subject variability was greater than the within-subject variability at the base (ratio 1.5) but not at the tip.

Relationship of NPTR Parameters to Age

Mean NPTR parameters for each decade are shown in Tables 1 and 2. Parameters relating to the duration of tumescence (Fig. 2) decreased linearly with age ($r = -0.55$ for TTT, $r = -0.57$ for TT/h, $r = -0.60$ for TT/epi; $p = 0.0001$). In addition, absolute (and fractional) δtum at the tip ($r = -0.41$, $p < 0.01$) and AUC-tumescence (tip, $r = -0.38$, $p < 0.01$; base $r = -0.33$, $p < 0.05$ [Fig. 3]) decreased significantly with age. However, sleep time, the number of episodes per session, the number of episodes per hour of sleep (Fig. 4), and measures of rigidity (maximum rigidity, AUC-rigidity [Fig. 3]) did not change significantly with age ($p < 0.08$).

The lower fifth percentile by decade for selected NPTR parameters is shown in Table 3. Since maximum tumescence (tip) did not fit a normal distribution, the lower fifth percentile was derived by linear extrapolation from the empirical distribution function (Fisher, 1969).

Other Relationships between NPTR Parameters

Maximum tumescence, AUC-tumescence, and AUC-rigidty were greater at the base than at the tip over all decades (Table 2). This same relationship between base and tip was noted for maximum rigidity and δtum, although subjects in the second decade (both parameters) and third decade (δtum only) had nearly equal values for base and tip. A significant correlation between tip and base was noted for maximum tumescence ($r = 0.31$, $p < 0.05$), maximum rigidity ($r = 0.62$, $p = 0.0001$), AUC-tumescence ($r = 0.82$, $p = 0.0001$), and AUC-rigidity ($r = 0.89$, $p = 0.0001$).

AUC-tumescence and AUC-rigidity were highly correlated at both tip ($r = 0.76$, $p = 0.0001$) and base ($r = 0.69$, $p = 0.0001$). Furthermore, a correlation existed between maximum tumescence and rigidity at the tip ($r = 0.312$, $p < 0.05$), but was of borderline significance at the base ($r = 0.26$, $p = 0.08$).

Discussion

The Rigiscan NPTR monitor provided highly reproducible measurements of penile tumescense

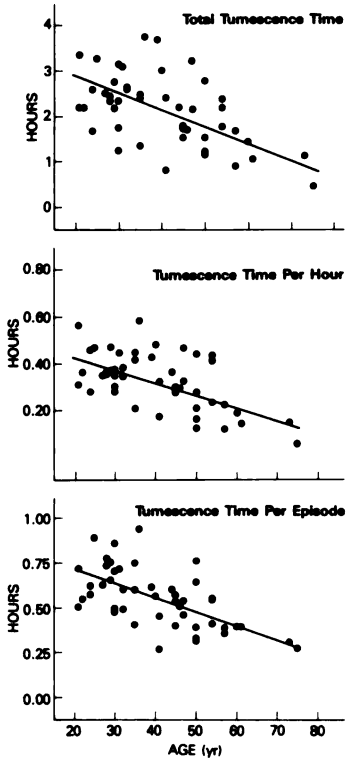

Fig. 2. Mean total tumescence time (top panel), tumescense time per hour sleep (middle panel), and tumescence time per erectile episode (bottom panel) are plotted against age for 47 normal males. All parameters correlated significantly with age ($p = 0.0001$).

and rigidity in this study of normal men. Because the monitor does not require a sleep laboratory, it can be used at home, which reduces the cost of testing and maximizes patient privacy. In contrast to previous studies of NPT conducted in sleep laboratories, this study did not observe a first-night effect (Karacan and Moore, 1986), and found that the data varied insignificantly from session-to-session. Although studies of NPTR without sleep monitoring could be misleading if sleep were disrupted (Pressman et al, 1986), the present results indicate a high degree of patient comfort with the instrument (94% of subjects completed three nights of study). An important feature of the instrument is its ability to record dynamic changes in rigidity, as opposed to static measurements of rigidity by axial buckling force (Karacan and Moore, 1986). Assessment of penile rigidity is particularly important since both tumescence and rigidity are needed for adequate sexual functioning (Wein et al, 1981).

In keeping with previous studies in normal men

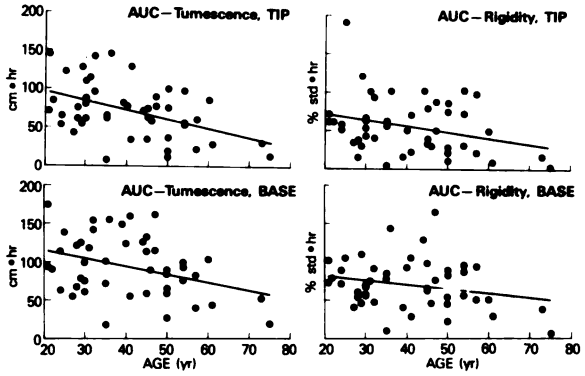

Fig. 3. Mean area-under-the-curve (AUC) values for tumescence (left panel) and rigidity (right panel), measured at the tip (upper graphs) and base (lower graphs), plotted against age for 47 normal males. Tumescence was significantly related to age ($p < 0.05$), whereas rigidity was not (p = NS).

(Karacan et al, 1976), this study found that total tumescence time declined significantly with age. In contrast to previous work (Karacan and Moore, 1986; Karacan et al, 1976), however, the number

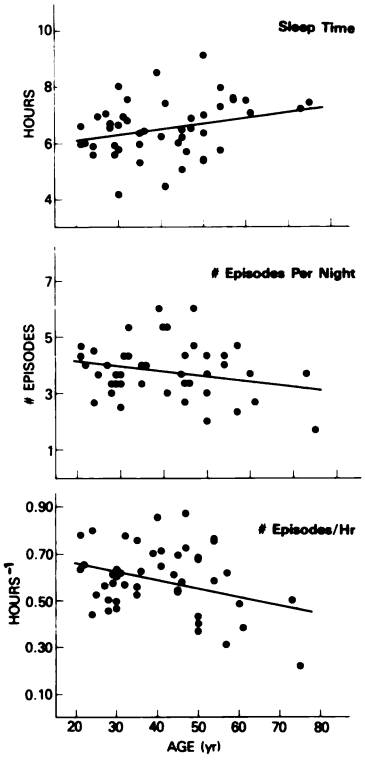

Fig. 4. Mean sleep time (top panel), the number of erectile episodes per night (middle panel), and the number of erectile episodes per hour sleep (bottom panel) are plotted against age for 47 normal males. None were significantly related to age (p = NS).

TABLE 3. Lower 5th Percentile of Selected NPTR Parameters by Decade

Age (year)	Episodes per Session	Total tumescence (hour)	Tumescence time per hour sleep	Δ −tumescence, tip (cm)	Maximum tumescence, tip (cm)	Area under the Curve, tumescence	
						tip (cm/hour)	base
20–29	2.4	1.50	0.25	3.6	9.8	35.2	45.8
30–39	2.3	1.17	0.20	3.4	9.6	23.7	35.3
40–49	2.1	0.83	0.14	3.1	9.2	11.5	24.1
50–59	1.9	0.47	0.09	2.8	8.9	<10	12.1
60–69	1.7	0.10	0.03	2.5	8.6	<10*	<10*
≥ 70	1.5	<0.10*	<0.03*	2.2	8.2	<10*	<10*
All subjects	2.2	0.79	0.13	3.1	8.7	12.7	26.9

*Small number of subjects in these groups did not permit a more precise estimation of value.

of erectile episodes per session did not significantly change with age. Surprisingly rigidity was not age-related. Observations of men in the seventh and eighth decades, however, were limited by a small sample size. AUC-rigidity was highly correlated with AUC-tumescence, confirming clinical and experimental observations (Lue and Tanagho, 1987) that tumescence and rigidity increase simultaneously during an erection. Similarly, although most measures at the base were greater than at the tip, the AUCs of tumescence and rigidity at the base and tip were highly correlated. Ratios of tip and base measures were also examined, but the ratios had unacceptably large replicate errors (data not shown).

The approach to interpretation of the NPTR phenomenon in the present study was quantitative rather than qualitative. The definition of an erectile episode was empiric; a more useful (but unknown) measurement would be the minimal tumescence and rigidity needed for vaginal penetration. Our definition allowed an erectile episode to be distinguished from noise in computer analysis of AUC. By quantitating tumescence and rigidity with AUC our study integrated duration and amplitude in a single measure and avoided overinterpreting single peaks, as occurs with maximum rigidity, for example (Fig. 1). Furthermore, AUC measurements, as well as total tumescence time and maximum tumescence, were among the most reliable NPTR parameters in an analysis of between-subject and within-subject variability.

The results indicate that the NPTR instrument used in this study is a highly reproducible new method for quantitating both rigidity and tumescence in normal men. However, we recognize that sleep records of NPTR may not precisely mimic waking erectile functioning. Prospective studies will allow us to determine the reliability of NPTR measurements in the diagnosis of erectile dysfunction.

Acknowledgments

The authors would like to acknowledge the Dacomed Corporation for their support and cooperation in developing software for AUC analysis of NPTR curves, and Dr. Julian Davidson for his encouragement and inspiration. They also would like to thank Ms. Nelly Rivera, Ms. Tannia Cartledge, and Ms. Teresa Bristow for their assistance, and Ms.Kathy Shoobridge for unsurpassed secretarial support.

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