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ORIGINAL ARTICLE

Comparison of international index of erectile function with nocturnal penile tumescence and rigidity testing in evaluation of erectile dysfunction

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We tried to compare the parameters of nocturnal penile tumescence and rigidity (NPTR) testing with erectile function (EF) domain score of International Index of Erectile Function (IIEF), which is used in diagnosis and determining the severity of erectile dysfunction (ED), and to assess the sufficiency of IIEF in the diagnosis of ED. A total of 90 men, mean age 46 years (24–75), presenting with ED to our clinic between January 2001 and March 2003 were included in the trial. All the men answered the standard IIEF (15 questions) forms and was divided into four groups as mild ED, moderate ED, severe ED and no ED according to the EF domain score that is obtained from 1st, 2nd, 3rd, 4th, 5th and 15th questions. Then NPTR testing with the RigiScan Plus monitoring device was performed for two consecutive nights on those men. The distribution of the six parameters of NPTR testing (number of erections, duration of erections, TAU base, RAU base, TAU tip, RAU tip) among the four groups and the correlation with IIEF-EF domain score were evaluated. Additionally, the distribution of the risk factors (diabetes mellitus, hypertension, atherosclerotic heart disease, dyslipidemia and smoking) was analyzed both among the four groups and in each group. According to IIEF-EF domain scores of 90 patients, 16 (18%) had severe ED, 21 (23%) moderate ED, 41 (46%) mild ED and 12 (13%) no ED. There was no statistically significant difference between the risk factors among the men in these groups ($P>0.05$). When the IIEF-EF domain scores were compared with parameters of NPTR testing, no statistically significant difference was obtained among ED groups (mild, moderate, severe) ($P>0.05$). However, we observed a statistically significant difference between three ED groups and no ED group ($P<0.05$). If NPTR testing is considered as a gold standard test, sensitivity, specificity, positive predictive value and negative predictive value of IIEF-EF domain score in ED diagnosis are 100, 17.9, 29.4 and 100% respectively. In conclusion, we did not observe a clinical correlation between IIEF-EF domain scores and NPTR parameters in the whole population; however, we observed that if IIEF-EF domain scores were normal, NPTR parameters were also normal. In other words, we can say that if the initial IIEF-EF domain scores are normal, then we do not have to perform NPTR testing. This could be helpful to make a cost-effective diagnosis.
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Introduction

It is quite difficult to make a standard algorithm for the diagnosis of erectile dysfunction (ED). Although only medical history and physical examination can be adequate in most cases, sometimes further tests can be required, preferably noninvasive methods. As most of the men with sexual dysfunction (orgasmic disorder, premature ejaculation, libido loss) present to clinics with ED, it is important for the clinicians to asses the nature and severity of sexual dysfunction, and to distinguish organic–psychogenic ED.

Although some psychological tests and questionnaires assessing ED have been designed for this purpose, clinicians do not use these commonly because of their complexity and consumption. Moreover, the results can be subjective as the data

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gained from these tests are related with the patient's socio-cultural level and education. However, since recently erectile function (EF) assessing questionnaires are commonly used to categorize the severity of ED and distinguish organic–psychogenic ED in most of clinical researches and medicine industry.

Today the International Index of Erectile Function (IIEF) is one of the most used and accepted questionnaires in the assessment of male sexual function. However, there are a few studies comparing this questionnaire with the other diagnostic methods for assessing its capacity in determining the presence and severity of ED.

In this study, we tried to compare the parameters of nocturnal penile tumescence and rigidity (NPTR) testing with EF domain score of IIEF and to assess the sufficiency of IIEF in the diagnosis of ED.

Materials and methods

A total of 90 men, mean age 46 years (24–75), presenting with ED to our clinic between January 2001 and March 2003 were included in the study. Existence of ED for at least 3 months and no medical treatment for ED were the only inclusion criteria. Subjects applying for evaluation of EF because of medicolegal reasons, men with depression and anxiety disorder or taking antidepressant, antipsychotic or anxiolitic medications and with a poor quality of sleep were excluded.

All patients were evaluated by a detailed medical–sexual history and physical examination (blood pressure, systemic and genital examination), and were questioned about coexisting systemic disorders and risk factors (age, smoking, diabetes mellitus, hypertension, atherosclerotic heart disease and dyslipidemia). Also, a biochemical analysis, including fasting plasma glucose (FPG), liver function tests, kidney function tests and lipid profile, was performed for all patients. Then the patients answered the Turkish version of the standard IIEF questionnaire (15 questions). An EF domain score was given to all patients according to the answers they gave for the 1st, 2nd, 3rd, 4th, 5th and 15th questions of IIEF. Patients were then divided into four groups, which are used to classify ED worldwide, according to EF domain scores:

- Group I: severe ED (score 6–10),
- Group II: moderate ED (score 11–16),
- Group III: mild ED (score 17–25),
- Group IV: no ED (score 26–30).

According to the study protocol, NPTR testing was performed at home for two consecutive nights using the RigiScan Plus monitoring device before and after the treatment. The RigiScan Plus monitoring device was applied on the patient's penis to record changes in penile tumescence and radial rigidity during the whole duration of each night. The RigiScan Plus software version 5.2, which was used in this study, is able to recognize erectile activity as an event following a 20% increase in the base loop circumference persisting for at least 3 min. Summary statistics provided by the software include the number of events detected and integrated time intensity area measures of tumescence (tumescence activity units (TAU)) and rigidity (rigidity activity units (RAU)). These two units of measurement, RAU and TAU, were developed to facilitate the interpretation of the time-dependent nature of rigidity and tumescence. RAU represents the product of the minutes spent at a given rigidity level, and rigidity level expressed in decimal form. This value is calculated on a point-by-point basis and summarized for the entire erectile event. Similarly, TAU represents the time of duration of an erectile event multiplied by the percentage increase of circumference (expressed as a decimal) over the estimated baseline tumescence. RAU and TAU for both tip and base measurements are calculated and evaluated separately.

After each monitoring period, all data were transferred to a personal computer. At the end of the study, data were analyzed with RigiScan Plus software version 5.2. The software recognizes an erectile event if there is a 20% increase in base loop circumference 3 min or more in duration. It also calculates TAU and RAU for each night separately. Sessions of less than 5 h duration were accepted as invalid and repeated. Erectile activity during sleep was measured by determining the following parameters: number of erectile events (with tip rigidity greater than 60% and longer than 10 min in duration) and TAU–RAU values.

The distribution of the six parameters of NPTR testing (number of erections, duration of erections, TAU base, RAU base, TAU tip, RAU tip) among the four groups and the correlation with IIEF-EF score were evaluated. Additionally, the distribution of the risk factors (diabetes mellitus, hypertension, atherosclerotic heart disease, dyslipidemia and smoking) was analyzed both among the four groups and in each group.

Statistical analysis was based on one-way ANOVA, Kruskal–Wallis variant analysis and χ^2 test where available. $P<0.05$ was considered as significant. SPSS for Windows Version 11.5 is used for statistical analysis.

Results

All the patients completed the protocol. Only two of the patients had NPTR testing for the third time as their measurements for the first two nights were less than 5 h duration. The mean age of the patients was 46 years (24–75) and the mean duration of the

symptoms was 19.8 months (3–84). Of the patients, 16 (18%) had severe ED (Group I), 21 (23%) moderate ED (Group II), 41 (46%) mild ED (Group III) and 12 (13%) no ED (Group IV). In other words, according to this questionnaire, 78 (87%) men had ED and 12 (13%) men were potent.

When the patients were analyzed for the risk factors, eight (8.9%) had atherosclerotic heart disease, 19 (21.1%) dyslipidemia, 21 (23.3%) hypertension, 34 (37.8%) diabetes mellitus and 58 (64.4%) smoking. No statistically significant difference was observed for the frequency of the risk factors both in each group and among the four groups ($P>0.05$) (Table 1). Also, no statistically significant difference was observed for the frequency of the risk factors between men with ED (score <26) and men without ED (score $\geqslant 26$) ($P>0.05$).

When the IIEF-EF scores were compared with parameters of NPTR testing (number of erections, duration of erections, TAU base, RAU base, TAU tip, RAU tip), no statistically significant difference was obtained among the three ED groups (mild, moderate, severe) ($P>0.05$). However, we observed a statistically significant difference between three ED groups and no ED group ($P<0.05$) (Table 2).

When the criteria that a man having an erection with a rigidity over 60% and a duration over 10 min in 8 h duration sleep period in NPTR testing is accepted as potent[1] is considered, of the 90 men, 67 (74.4%) were potent and 23 (25.6%) were impotent. Nevertheless, according to IIEF-EF domain scores 78 men (87%) had ED and 12 men (13%) were potent. In other words, of the 78 men being considered as having ED according to IIEF, 55 had normal EF according to NPTR testing. When the IIEF forms of these patients were evaluated again, it is observed that some of them (38%) had a sexual function disorder like libido loss, ejaculatuar–orgasmic disorders and inadequate intercourse satisfaction.

If the NPTR testing is considered as a gold standard method for assessing the presence and severity of ED, and distinguishing organic–psychogenic ED,[2] sensitivity, specificity and positive predictive value (PPV) of IIEF are 100, 17.9 and 29.4%, respectively, when compared to NPTR testing. However, all the men (*n*: 12) evaluated as having no ED according to IIEF have normal NPTR testing; thus negative predictive value (NPV) of IIEF is 100% (Table 3).

Discussion

ED is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual activity.[3] In fact, it has been noted that ED is 'the most common sexual dysfunction among men who seek help for sexual problems'.[4] It is estimated that ED affects as many as 152 million men worldwide.[5] Evidence-based approaches in the diagnosis of ED have included cavernosometry, NPTR testing and

Table 1 Distribution of risk factors

Risk factors	*Group I (6–10)*	*Group II (11–16)*	*Group III (17–25)*	*Group IV (26–30)*	P-*value*
Dyslipidemia	18.8%	33.3%	17.1%	16.7%	>0.05
ASHD	12.5%	9.5%	9.8%	0	>0.05
Diabetes mellitus	31.3%	47.6%	36.6%	33.3%	>0.05
Hypertension	18.8%	14.3%	34.1%	8.3%	>0.05
Smoking	68.8%	71.4%	63.4%	50%	>0.05
Age (years)	47	49	47	44	>0.05

Table 3 Number of patients taking diagnose according to IIEF and NPTR

	Confirmation (NPTR testing)		
	With ED	*Without ED*	*Total*
IIEF–EF score			
With ED	23	55	78
Without ED	0	12	12
Total	23	67	90

Table 2 Distribution of NPTR parameters

	Group I (6–10)		*Group II (11–16)*		*Group III (17–25)*		*Group IV (26–30)*	
NPTR parameters	*X*±*s.d.*	*Median (min–max)*	*X*±*s.d.*	*Median (min–max)*	*X*±*s.d.*	*Median (min–max)*	*X*±*s.d.*	*Median (min–max)*
No. of erections (per night)	1.06±1.24	0.5 (0–3)	1.24±0.94	1 (0–3)	1.59±1.28	2 (0–5)	3.17±1.11	3 (1–5)
Duration of erections (min)	28.25±27.79	18.5 (0–81)	32.47±27.31	24 (0–91)	34.95±32.64	25 (0–157)	63.41±32.25	54 (20–123)
RAU tip	29.25±27.80	20 (0–90)	34.66±27.12	30 (0–102)	37.80±31.66	34 (0–146)	66.83±28.57	64 (25–116)
TAU tip	14.50±12.74	8 (0–36)	14.95±11.46	13 (0–41)	16.90±13.85	13 (0–58)	28.75±15.08	28 (9–60)
RAU base	28.87±20.73	22 (0–60)	33.23±25.68	31 (0–111)	39.80±30.81	30 (0–119)	63.33±22.84	62 (31–100)
TAU base	17.31±12.52	16 (0–41)	22.90±16.5	20 (0–63)	25.39±18.08	23 (0–77)	42.08±14.38	38 (22–67)

penile blood flow studies. Although laboratory-based diagnostic procedures are available, recently sexual questionnaires have gradually replaced them for evaluating ED as they are easy to use.

IIEF, a 15-item self-administered questionnaire scale, is a brief and reliable measure of ED that is culturally, linguistically and psychometrically valid.[6] The IIEF has been widely used to categorize the severity of ED and distinguish organic–psychogenic ED, and determine the efficacy of treatments in most clinical researches. Rosen *et al*.[6] showed the IIEF to be a sensitive and specific tool for investigating male sexual dysfunction.

The usefulness of monitoring NPTR in the evaluation of impotence is based on the findings of Karacan[7] and Fisher *et al*.[8] that erections occur at night during rapid eye movement sleep. The RigiScan Plus monitor is a useful and convenient tool in the evaluation of male sexual dysfunction. It enhances earlier studies of nocturnal penile tumescence by providing information on rigidity. It should be recognized that this is a clinical tool and not a quantitative research tool.[9]

To our knowledge, this is the first study in the literature that compares the IIEF-EF domain scores with NPTR testing in the evaluation of ED. In the present study, when we compared the IIEF-EF domain scores with the NPTR findings, only 29.4% (23 of 78) of men diagnosed as having ED according to IIEF had a diagnosis of ED with NPTR testing, and no statistically significant difference was observed among ED groups (mild, moderate, severe) ($P>0.05$). However, we observed a statistically significant difference between three ED groups and no ED group ($P<0.05$). These two findings suggest that IIEF is inadequate in diagnosis and determining the severity of ED. This result is harmonious with that of Kassouf and Carrier,[10] who evaluated the ability of the five-item version of IIEF to diagnose the vascular etiology and severity of ED, and compared it with pharmacological testing and duplex Doppler ultrasonography.

Although we did not observe a clinical correlation between IIEF-EF domain scores and NPTR parameters in the whole population, we observed that if IIEF-EF domain scores were normal, NPTR parameters were also normal. There is a very poor correlation of NPTR results with any degree of ED by IIEF. In other words, we can say that if the initial IIEF-EF domain scores are normal, then we do not have to perform NPTR testing. This could be helpful to make a cost-effective diagnosis.

In conclusion, IIEF is still a useful tool in the initial evaluation of ED as it is an inexpensive method and can be easily applied. It can be used especially to assess the changes over time in a patient in clinical trials and drug researches as it has a high degree of internal consistency. It can also be helpful to the clinician in determining the nature of sexual dysfunction (orgasmic disorder, premature ejaculation, libido loss) and in clinical diagnostic algorithms.

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