

ORIGINAL RESEARCH

Evaluating the results of Nocturnal Penile Tumescence test utilizing Iranian erection analyzer - a case control study

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Abstract: Background: Erectile dysfunction (ED) is a male sexual condition that affects 10% to 25% of men globally. Identifying the underlying cause of ED in males is a critical aspect of diagnosis. For many years, the RigiScan® devices have been utilized to distinguish between psychological and physiological erectile dysfunction. The purpose of this study was to look at the validity of an Iranian erection analyzer equipment for evaluating nocturnal penile tumescence (NPT) in ED patients referred to Shahada-e-Tajrish Hospital in 2021. Materials and Methods: Patients who were diagnosed with vascular erectile dysfunction by doppler ultrasound evaluation and intracavernosal injection (ICI) test were included in this study. Also, a group of sexually healthy volunteers were included in the study as a control group. After receiving written informed consent, both groups were evaluated for two nights with the NPT test with the Iranian Erection Analyzer device. The results of the two groups were collected and analyzed. Results: A total of 45 patients with erectile dysfunction and 29 sexually healthy individuals were included in the study. Both groups were hospitalized for two nights in the isolation room of the urology ward and the NPT test was performed for them. Our results showed that the NPT test performed by the Iranian Erection Analyzer device with 62% sensitivity and 100% specificity is capable of distinguishing patients with erectile dysfunction from sexually healthy men. Conclusions: Based on our results, the Iranian Erection Analyzer device is accurate enough to diagnose patients with erectile dysfunction and can be used in clinics.

Keywords: Erectile Dysfunction; Erection; Male Impotence; Penile Tumescence

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1. Introduction

Erectile dysfunction (ED) is a male sexual problem that impacts 25% of men worldwide (1). ED is characterized by the inability to achieve a stable and maintained erection and achieve satisfactory sexual performance, which may result from inadequate erection and ejaculation disorders. The process of achieving an erection is a complex phenomenon that is due to a delicate and coordinated balance between neural, vascular, and tissue components. ED can have significant impacts on both physical and mental health, as well as on the quality of life of affected individuals and their partners (2-4).

One important aspect of managing ED is identifying the underlying cause of the disorder in men, which may involve the use of the RigiScan® device to assess penile erectile capacity. The Nocturnal penile tumescence (NPT) test is a non-invasive method for detecting the erectile capacity of the penis, that measures both erection and stiffness in the penis simultaneously (5, 6). In general, NPT occurs during rapid eye movement sleep, in healthy males. To measure NPT, the RigiScan® monitoring test has been suggested due to its convenient, cost-effective, and home-based monitoring capabilities (1). By this test, clinicians can differentiate between psychologic or organic causes of ED. However, due to the diversity of sexual dysfunctions and their varying prevalence in different populations, there is a need for validation of NPT assessment devices in specific populations.

To address this need, the present study aimed to investigate the accuracy of an Iranian erection analyzer device for evaluating NPT in patients with ED referred to Shahada-e-Tajrish

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Hospital in 2021. This study may provide important insights into the use of NPT assessment devices in this population and contribute to the development of effective management strategies for ED.

2. Patients and methods

Patients who were referred to the urology clinic of Shohada-e-Tajrish Hospital with complaints of erectile dysfunction in 2021 were investigated. Patients who had a score of less than 30 based on the IIEF15 questionnaire, were subjected to additional examination with Doppler ultrasound and Intra-cavernosal injection (ICI) test. Patients who had a peak systolic velocity (PSV) less than 25 cm/s and did not have an erection after intra-cavernosal papaverine injection were included in the study as vascular erectile dysfunction. These patients were used to assess the sensitivity of the device and several age-matched sexually healthy volunteers were invited to participate in the study as a control group to assess the specificity.

Exclusion criteria: Presence of underlying conditions such as depression and generalized anxiety, sleep disorders, utilization of medications affecting erection, drug or alcohol addiction, known cases of diabetes mellitus.

After obtaining consent from the participants, both groups were examined with the Iranian erection analyzer device (Produced by Hursun-Saman-Pars Company) similar to the RigiScan® device for two nights. The participants were admitted for two consecutive nights to perform the test in the isolation room in the urology ward of the hospital.

If the participant's sleep quality is not satisfactory for interpreting the results of the NPT test, the test will be repeated on future nights. If the participant does not agree to continue his cooperation, he will be excluded from the study. The minimum amount of radial rigidity, the minimum number of penile tumescence and the minimum time of tumescence for each episode, 70%, 1 episode per night and 15 minutes, were defined as the absence of erectile dysfunction in results. (7)

The results of the NPT test were analyzed and the sensitivity and specificity of the erection analyzer device were assessed.

2.1. Ethical issues

The research conducted in this study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (Ethical code No. IR.SBMU.MSP.REC.1400.647). Before any intervention, all participants provided written informed consent.

3. Results

Finally, 74 individuals including 45 participants with erectile dysfunction and 29 age-matched healthy volunteers as a control group were included in the study. The mean age of the

case group participants was 34.44 ± 6.91 years. The mean age of the control group participants was 31.59 ± 6.08 which didn't have significant differences. We also examined other clinical and demographic factors and found no significant differences between the two groups (Table 1).

Both groups were examined with an Iranian erection analyzer for two nights. We found that the erection analyzer device in the case group (suffering from erectile dysfunction) correctly diagnosed 28 individuals (62.22%) with erectile dysfunction, and the results of 17 individuals (37.78%) were falsely incorrect. In the control group (sexually healthy), the NPT test results were completely consistent with the individuals' conditions (100%), and normal erectile function was reported for all participants.

These results showed 62.22% sensitivity and 100% specificity for the NPT test performed by the Iranian erection analyzer (Table 2).

4. Discussion

Our results showed that the NPT test performed by the Iranian Erection Analyzer has a sensitivity of 62% and a specificity of 100%.

In this study, the normal values for the NPT test were defined based on a recently published study on Iranian men (7). Several studies have been conducted in different communities to determine the normal values of the NPT test, which reported different results based on different races (8, 9). For example, only one tumescence episode with stiffness greater than 70%, even for 5 minutes reported as normal by Bennett et al in 1996 (10). Also, in a study published by Licht et al., it was found that the commonly recognized standard for defining normal erection overestimates the prevalence of organic erectile dysfunction (11).

The RigiScan® device has been used for many years to differentiate psychological erectile dysfunction from physiological erectile dysfunction (12, 13). In 2017, Nagao et al. published a study on 46 men aged 17 to 65 years to investigate the usefulness of the RigiScan® device. In this study, patients were divided into two groups. The erectile function of 20 participants was evaluated by the RigiScan® device and 26 participants by both the RigiScan® device and ICI test. Their results showed that when assessing erectile function, the RigiScan® assessment of NPT outperforms ICI alone (14).

It is worth mentioning that some scientists are skeptical about the RigiScan® device's utility and cost-effectiveness (15, 16). In a study conducted in 2018 by Wang et al on 1169 patients with ED in China, it was found that the use of the Audiovisual Sexual Stimulation and RigiScan® test is more accurate in diagnosing physiological erectile dysfunction (17). Also, in the article published by Edgar et al., a new method using five sensors is proposed to evaluate nocturnal erec-

Table 1: Comparison of clinical and demographic features between two groups

	Case	control	P-value
Mean Age(years)	34.44	31.59	0.062
Mean Weight (Kg)	80.76	80.57	0.791
Mean Height (Cm)	173.52	174.65	0.441
Mean BMI*	26.82	26.40	0.423
Mean SBP**	127.60	124.49	0.365
Mean DBP***	80.00	78.98	0.431

* Body mass index
 ** Systolic blood pressure
 *** Diastolic blood pressure

Table 2: The accuracy of Nocturnal penile tumescence test results performed with the Iranian erection analyzer

	Nocturnal penile tumescence test results		Sensitivity	Specificity	Positive predic- tive values	Negative predic- tive values
	Normal erectile function	Erectile dys- function				
Case group (45 participants with erectile dysfunction)	17 individuals	28 individuals	62.22%	100%	100%	88.82%
control group (29 sexually healthy participants)	29 individuals	0 individuals				

tions, which can lead to more accurate results (18). Despite all the mentioned issues, RigiScan® is still widely used in diagnostic centers to evaluate erectile dysfunction. The results of our study showed that the NPT test performed by the Iranian Erection Analyzer device has an acceptable sensitivity and specificity for the evaluation of erection disorders, multi-center studies with a larger population are suggested to achieve more accurate results.

5. Conclusions

The results of the present study determined that the NPT test performed by the Iranian erection analyzer device with a sensitivity of 62% and a specificity of 100% is capable of distinguishing patients with erectile dysfunction from sexually healthy men.

6. Appendix

6.1. Acknowledgment

None.

6.2. Conflict of Interest

None.

6.3. Funding and supports

None.

6.4. Authors contributions

None.

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