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Original Article

A Comparison of the International Index of Erectile Function and Measurement of Nocturnal Penile Tumescence Using the Androscan MIT Device

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Abstract

Purpose: To determine the agreement between two erectile dysfunction (ED) diagnostic methods, International Index of Erectile Function-15 (IIEF-15) questionnaire and "Androscan MIT" night penile tumescence recorder. **Materials and Methods:** An assessment of ED in 40 patients (age, 25–60 years) was performed using the "Androscan MIT" device and IIEF-15 questionnaire (erectile domain). Cohen's kappa coefficient and receiver operating characteristic (ROC) analyses were used to examine the difference between "Androscan MIT" and IIEF-15 questionnaire results. During ROC-analyses "Androscan MIT" results were considered the gold standard for ED diagnosis. **Results:** "Androscan MIT" results had a significant but weak positive correlation with IIEF-15 questionnaire (kappa value = 0.333, $P < 0.01$). Based on the ROC-analyses, it was found that the sensitivity and specificity of the IIEF-15 questionnaire for severe ED according to "Androscan MIT" were 100% and 55.9%, respectively. The sensitivity and specificity of the IIEF-15 questionnaire for moderate ED according to "Androscan MIT" were 63.2% and 57.1%, and for mild ED, 23.1% and 33.3% respectively. The lowest accuracy of the IIEF-15 questionnaire was for patients with normal erectile function (sensitivity and specificity were 0% and 44.7%, respectively). **Conclusion:** The agreement between the objective and subjective diagnosis of ED remains low. At the same time, the lower severity of ED according to "Androscan MIT" is associated with less diagnostic value of IIEF-15.

Keywords: Androscan MIT, comparison, erectile dysfunction, International Index of Erectile Function-15

Introduction

Nowadays, the diagnosis of erectile dysfunction (ED) is mainly based on the subjective assessment of erectile function, which is usually detected using questionnaires.[1] The International Index of Erectile Function, consisting of 15 questions (IIEF-15), particularly its erectile domain, is the most commonly used questionnaire,

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and the so-called "gold standard," for the detection of various degrees of ED.[1,2]

Despite its availability, the use of the IIEF-15 questionnaire can be challenging due to the inclusion of patients with psychogenic disorders in the ED group, which leads to the unjustified prescription of drug therapy bypassing the main etiological factor of ED.[3] The RigiScan device is used to objectify the complaints of patients with ED abroad, which enables the objective diagnosis of organic ED by recording the quality of nocturnal penile tumescence.[4] It was previously shown that absence of nocturnal erections indicates an organic cause of ED, whereas the presence of nocturnal erections indicates normal penile function.[5] According to Edgar *et al.* (2022), RigiScan is the golden standard for monitoring nocturnal erections and distinguishing between psychogenic and organic causes.[6]

The Russian analog of the RigiScan device is the Androscan MIT [Figure 1], which was registered to the Russian State Register of Medical Devices in November 2018. In contrast to its foreign analog, which determines the rigidity of the penis, the Russian recorder evaluates the change in the diameter of the penis at the base and also determines the ratio of the penile diameter in the nonerect and erect states.[7] The main advantages of Androscan MIT are its simplicity and cost-effectiveness, as well as the fact that studies can be performed on an outpatient basis, and thus in a familiar for the patient environment. It is believed that such an objective assessment of erectile function contributes to the earlier detection of ED, and is also suitable for evaluating therapeutic effectiveness, thereby increasing the odds of timely selecting an optimal treatment option.[8]

The growing desire for objectification makes it necessary to compare objective and generally accepted, yet subjective, methods for the assessment of erectile function. However, there are only few publications in literature focusing on this topic.[9-11] It was found that the results of the ED assessment using the RigiScan device are slightly inconsistent with the data of the IIEF-15 questionnaire, revealing a weak correlation or complete absence between the parameters of each measurement method.[9,10] Similar comparisons for the Russian analog Androscan MIT device have not been conducted before. Thus, the aim of this study was to assess the agreement between the results obtained using the IIEF-15 questionnaire and the "Androscan MIT" night penile tumescence recorder in the diagnosis of ED.

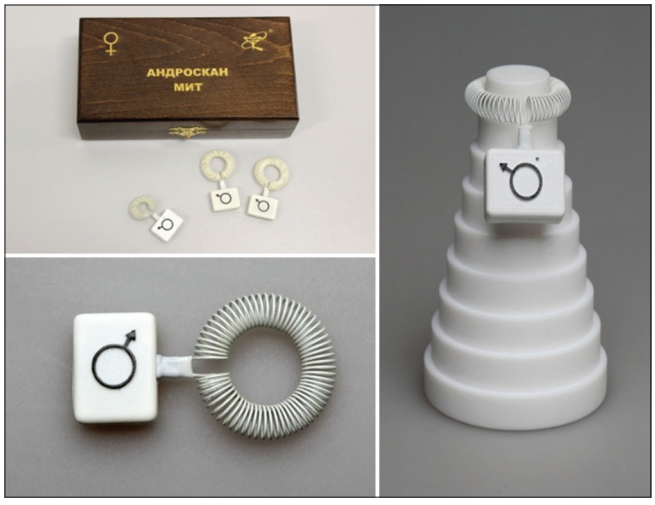

Figure 1: The Androscan MIT

Materials and Methods

Study sample

The study included 40 patients examined on the basis of the Moscow State University Medical Center for ED. All patients signed informed consent to participate in the study. The study was approved by the Local Ethics Committee of MSU University Clinic (approval number 14 and approval date 21.12.2020). The study period was 6 months from February 2021 to July 2021.

Inclusion criteria involved individuals aged between 45 and 60 years with willingness to have their erectile quality assessed. The exclusion criteria were as follows: the presence of sexually transmitted diseases, inflammatory diseases of the genitals and lower urinary tract, and psychogenic ED. Erectile function was assessed by two methods: using the Androscan MIT device and the IIEF-15 questionnaire (erectile domain). According to IIEF-15, ED severity was classified into four diagnostic categories: no ED (EF score 26–30), mild ED (EF score 17–25), moderate (EF score 11–16), and severe (EF score 6–10).[12]

To interpret androscanning indicators, the criteria developed by Kamalov and Chaliy *et al*. were used[13] [Figure 2].

Equipment

For an objective assessment of ED, the Androscan MIT device was used, which is an easily put-on miniature, autonomous, wireless registration device with a processor, memory, and autonomous power supply [Figure 1]. NPT with Androscan MIT device was monitored for two consecutive nights. The penile diameter was registered every 10 s for 12 h following sensor activation. After the study was completed, the device was connected to the reader via a wireless communication channel to read the accumulated data. The reader was connected to a personal computer using a standard USB cable, and the number of studies that can be performed with a single sensor (after standard processing) is 20. The main advantages of using the Androscan MIT device include the simplicity and cheapness of the method, as well as the fact that the study is carried out on an outpatient basis, in a familiar environment for the patient. The main disadvantage of using this method involves potential software failures, which, however, are promptly eliminated by the developer.

Statistical analysis

The data were collected using the Microsoft Excel package (version 12.2.4). Statistical data processing was performed using the STATISTICA12 (StatSoft, Russia,

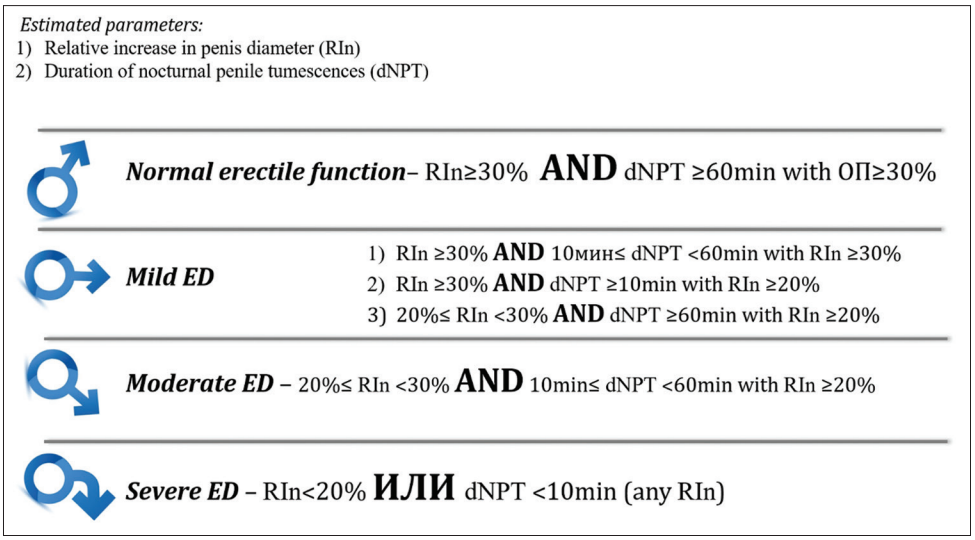

Figure 2: Normative criteria for evaluating erectograms obtained by monitoring nocturnal penile tumescences using the Androscan MIT device[11]

2015) and IBM SPSS Statistics version 26.0.0.0 (IBM, USA, New-York 2019) software. Continuous clinical parameters were presented as mean ± standard deviation. To assess the agreement of the two methods in terms of determining the degree of ED, the Cohen's kappa coefficient was calculated. To interpret Cohen's kappa, the method of Landis and Koch (1977) was used: kappa coefficient of ≤0.20 shows no agreement, 0.21–0.40 shows weak agreement, 0.41–0.60 shows moderate agreement, 0.61–0.80 shows significant agreement, and 0.81 shows almost complete agreement.[10] Receiver operating characteristic (ROC) analysis was used to compare the effectiveness of the two methods, where the results of androscanning were accepted as the "gold standard" for the ED diagnosis. $P < 0.05$ was considered statistically significant.

Results

The study included 40 patients aged 45 to 60 years (mean, 50.0 ± 8.35 years). The mean IIEF-15 score was 16.55 ± 4.55. Cohen's kappa coefficient analysis revealed a significant disagreement with respect to the degree of ED between the IIEF-15 questionnaire and Androscan data. The Cohen's kappa value was 0.333, indicating a weak but significant agreement between the two methods for assessing the degree of erectile function ($P = 0.003$).

ROC analysis revealed that the highest accuracy of the subjective assessment of the degree of ED is characteristic of severe ED, while the lowest is observed in the absence of ED [Figure 3 and Table 1]. The sensitivity and specificity of the IIEF-15 questionnaire results for severe ED according to the Androscan data were 100% and 55.9%, respectively, and the largest area under the ROC curve (0.86) corresponded to the best quality of the proposed model (0.73). In addition, a pattern was found: mild erectile disorders in the androscanning data were associated with less accurate IIEF-15 questionnaire results [Table 1]. For moderate ED, the sensitivity and specificity of the IIEF-15 questionnaire according to the Androscan data

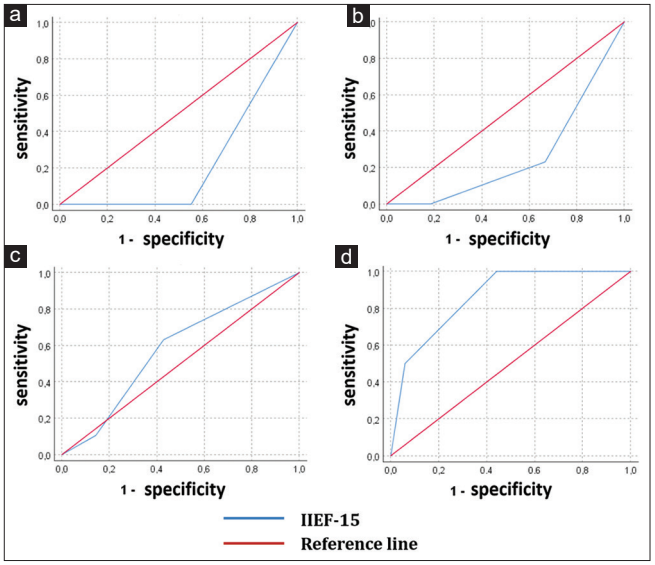

Figure 3: ROC-curves showing the predictive function of the ED degree according to Androscan data based on the results of IIEF-15: (a) A-state variable 0 (no ED); (b) B-state variable 1 (mild ED according to Androscan data); (c) C-state variable 2 (moderate ED according to Androscan data); (d) D-state variable 3 (severe ED according to Androscan data). ROC: Receiver operating characteristic, IIEF-15: International Index of Erectile Function-15, ED: Erectile dysfunction

were 63.2% and 57.1%, respectively, and for mild ED, these values decreased to 23.1% and 33.3%, respectively. The lowest accuracy of the IIEF-15 questionnaire was typical for patients with normal erectile function (sensitivity and specificity were 0% and 44.7%, respectively). The ROC analysis data are presented in Table 1.

Discussion

ED is the inability to achieve or maintain an erection sufficient to perform sexual intercourse. According to official data in the Russian Federation, up to 50% of men aged 20 to

Table 1: Receiver operating characteristic analysis comparing the effectiveness of the International Index of Erectile Function-15 questionnaire and Androscan results

Parameter	ED degree (Androscan data)			
	No ED (*n*=7)	Mild ED (*n*=8)	Moderate ED (*n*=19)	Severe ED (*n*=6)
Area under ROC curve	0.224	0.261	0.579	0.86
Sensitivity (%)	0	23.1	63.2	100
Specificity (%)	44.7	33.3	57.1	55.9
Quality of model	0.01	0.1	0.4	0.73

ROC: Receiver operating characteristic, ED: Erectile dysfunction

77 years suffer from ED, and most of the subjects report mild ED.[14] According to the European Association of Urologists, approximately 52% of men aged 40 to 70 years have problems with erectile function.[15] One of the scientifically based objective approaches to the diagnosis of ED is the registration of NPT.[16] RigiScan Plus is the most widely accepted and one of the most reliable tools to differentiate organic from psychogenic causes.[17] In Russia, Androscan MIT is a simple and low-cost method for NPT, which allows the examination to be performed on an outpatient basis.[13] To date, this technique has been unfortunately replaced in routine clinical practice by fast and economical subjective questionnaires, the most common of which is IIEF-15.[18] Nevertheless, there is not always an agreement between the data obtained from IIEF-15 and the analysis of NPT, despite the same tendency to normalization with medical therapy.[19] The first study evaluating the agreement between the two methods was conducted by Tokatli *et al*. in 2006 using the RigiScan Plus device.[9] It was found that there was no statistically significant relationship between the IIEF-15 questionnaire scores and the parameters recorded when monitoring nocturnal penile tumescence. According to RigiScan Plus, 74.4% of patients had normal erectile function, and 25.6% had ED, results which contradicted the results of IIEF-15 (13% and 87%, respectively), indicating significant errors in assessing erections based on the questionnaire method. Calculating the sensitivity and specificity of measuring nocturnal penile tumescence has been recognized as the gold standard for the diagnosis of ED. Based on this, the sensitivity and specificity of IIEF-15 were 100% and 17.9%, respectively.[9] A similar study was conducted by Yang *et al*. in 2006.[11] In the first experiment, the criterion for ED diagnosis based on the RigiScan test was the presence of at least one erection with a rigidity at the tip and base of more than 70% for a duration of 10 min or more. In the second experiment, normal erectile function was defined as penile rigidity of more than 60% for a duration of 10 min or more. In each case, a statistically significant positive correlation was found between the IIEF-15 and the RigiScan test data, but the correlation coefficient was low (r = 0.27 and r = 0.29, respectively), indicating the weak degree of correlation between the studied parameters.[11] Similar results were obtained by Melman *et al*.[10] Normal parameters of the RigiScan test were detected in 78% of patients, as opposed to the subjective data of IIEF-15 in which all patients had ED. The correlation coefficient between the measurement parameters of nocturnal penile tumescence (tip and base diameters and rigidity during erection) and IIEF-15 did not exceed 0.29, indicating that there was no relationship between the studied parameters, which makes a conclusion about the primary role of objective methods for diagnosing ED.[10] The data obtained by foreign researchers also confirmed these findings. The agreement between the two methods in measuring ED remained low (Cohen's kappa value of 0.333). At the same time, there was a tendency to deliberately conceal or conversely aggravate the state of erection, which may be associated with embarrassment or with the desire to commence treatment immediately even if not indicated. Only in severe ED cases men openly admit their problem, that was confirmed by the Androscan data (IIEF-15 sensitivity in severe ED was 100%).

A successful surgical intervention, use of related medications, or improvement of living conditions can affect the subjective improvement of erectile function, which is associated with a sense of security and concern for the individual state of health. In contrast, objective diagnostic methods may not demonstrate changes in erectile function. Thus, when investigating the effect of atorvastatin on erectile function, it was found that after long-term statin use, penile rigidity increased synchronously with the increase in the number of points of the IIEF-15 questionnaire according to the RigiScan test. Furthermore, the duration of erections and the volume of the penis remained unchanged compared to changes in the IIEF-15 indicators.[20] The absence of synchronous changes in the parameters of the RigiScan test and the IIEF-15 questionnaire was also noted in a study by Yang C.C. *et al*. (2006) The use of the head-preserving technique in penile cancer surgery resulted in an increase in IIEF-15 scores without a significant change in the RigiScan parameters, indicating the presence of a subjective component expressed by the successful outcome of organ-preserving surgery.[21] When studying the effect of the saddle nose of a bicycle on the possibility of urogenital paresthesia and ED assessed, results from the IIEF-15 questionnaire and the RigiScan device were not found to be compatible. During 6 months of the experiment, the study volunteers used a bicycle seat without a nose after which they noted a significant improvement in erectile function according to IIEF-15, while the parameters for measuring nocturnal penile tumescence did not change during the observation period. The latter once again confirms the presence of a subjective improvement when evaluating ED with the IIEF-15 questionnaire due to the absence of the blind component of the study.[22] This lack of correlation between all the studied indicators of objective and subjective assessment of erection may explain the significant disagreement between the results of the two methods as confirmed in this study.

Our study has a number of limitations. First of all, it is a study sample, and thus our data do not allow clear conclusions to be drawn. Second, a control group was absent when using

golden standard for ED diagnosis. However, there is no perfect golden standard for organic ED and NPT, and Androscan could become a novel objective method that is noninvasive and has low-cost.

Conclusion

Despite the widespread use of the IIEF-15 questionnaire as a diagnostic method for assessing the degree of ED, agreement of objective data obtained with the Androscan MIT device and data of subjective assessments of erectile function remains low. At the same time, milder erectile disorders are associated with less accurate results on the basis of the IIEF-15 questionnaire according to the Androscan results. On the contrary, the issue of constraint in severe ED was pushed to the background by the need to correct existing disorders, which led to 100% sensitivity in the IIEF-15 questionnaire.

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Conflicts of interest

There are no conflicts of interest.

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