Original paper

Nocturnal Electrobioimpedance Volumetric Assessment (NEVA®): an alternative for determining the quality of nocturnal erections

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Abstract

Objectives: The NEVA® device (Urometrics, Inc) measures changes in penile blood flow during nocturnal erections and enables one to make the diagnosis of either arterial insufficiency or venous leakage. The RigiScan® (Osbon Medical Systems) determines the quality of nocturnal erections to establish the organic or psychogenic nature of erectile dysfunction (ED) without indicating the nature of the impotence. This study compares both devices and tries to answer two questions. Does NEVA® give information on nocturnal erections comparable to that provided by the RigiScan®? What is the diagnostic capacity of NEVA® when compared to a comprehensive approach including laboratory examinations, psychological evaluation, intra-cavernous injection, and Duplex Doppler?

Material and methods: Twenty-five men with complaints of ED were enrolled in our study. Each of them had a complete work-up. This included the use of the RigiScan® for two consecutive nights. Then the NEVA® and RigiScan® devices were used simultaneously for the third night. The dynamic data provided by the NEVA® system were compared to the conventional nocturnal penile tumescence testing by means of the RigiScan®.

Results: An analysis of all sessions shows that all night recordings are comparable. The mean number of erections/night (2.80±0.34 vs 2.76±0.31) does not differ statistically significantly between NEVA® and RigiScan® assessments. Also the mean duration of events (30.66±1.92 minutes vs 25.63±1.62 minutes) does not differ. Normal axial rigidity by NEVA® (>200% change over baseline) correlates with all grade III erections by RigiScan®. The analysis of NEVA® data gives in 84% of the cases the same diagnosis of ED as that made after a complete work-up.

Conclusions: The present study demonstrates that electrobioimpedance registration has a good correlation with conventional penile tumescence testing. The analysis of data obtained with the NEVA® device seems to be an important and easy method for predicting the etiology of ED. For the assessment of the performance of the male partner during a sexual intercourse the registration of axial rigidity is a more important parameter than radial rigidity.

Key words: erectile dysfunction, NEVA, nocturnal penile tumescence and rigidity.

Introduction

Erectile dysfunction (ED) affects millions of men throughout the world [1-3]. It can have a strong, negative effect on the well-being and quality of life.

The advantage in clinical practice of oral agents with good efficacy and safety profiles for treating ED has very much changed the approach to this problem. According to the literature, a large percentage of patients affected are pleased with this therapeutic modality [4]. But one should not be tempted to prescribe such a "magic" pill before having completed the patient's work-up [5]. Identification of the etiology of ED allows to match the therapy to the underlying cause. Nocturnal electrobioimpedance volumetric assessment (NEVA®) of the penis is a diagnostic procedure that has previously been demonstrated to measure penile length, cross-sectional area and volume during spontaneous nocturnal erections in a small population with and without a history of ED [6, 7]. Nowadays nocturnal penile tumescence and rigidity (NPTR) monitoring is still used to determine the quality of nocturnal erections, especially in the cases where the organic versus psychogenic origin of the impotence is questioned or needed for insurance purposes. Differentiation between the causes of organic impotence is impossible with NPTR recording [8]. The present study suggests that the use of NEVA® can replace that of the RigiScan® for establishing the diagnosis of impotence. Two important questions should be answered: 1. Does NEVA® give information that is comparable to that provided by the use of the RigiScan®? 2. Does NEVA® provide more detailed information with regard to the etiology?

Material and methods

A total of 25 patients with ED were selected. All had a complete diagnostic work-up for their dysfunction. A clinical history was taken. Physical examination and a hormonal evaluation were carried out in all patients. An intracavernous prostaglandin E1 (PGE1) injection test (20 µg) and a penile duplex Doppler examination were performed. The patient was considered to have an arterial disease if the maximum systolic flow in the cavernous arteries was below 30 cm/s, and to have a venous problem when the maximum diastolic flow was over 5 cm/s [9-10]. Dynamic cavernosometry-cavernosography was done in all patients with suspected venous leakage. Each man used the RigiScan® device for three consecutive nights. The last night the patient was instructed to use the NEVA® device simultaneously. The latter system consisted of three electrode sets and a small recorder. One set of electrodes was applied to the base of the penis, another set was placed subcoronally, and a reference electrode was placed on the hip. Attention was given to the consistent and identical placements of the NEVA® electrodes and RigiScan® loops, which were placed by the same nurse. The NEVA® recorder and the RigiScan® unit were worn comfortably on the upper thigh.

RigiScan® and NEVA® data were downloaded to a host computer for further analysis at the completion of the study period. For RigiScan® evaluation, we used Johnsons' criteria of rigidity. Knoll and Billups' algorithm was used to study the NEVA® data [6]. Erectile events longer than 15 minutes were used to analyse the % volume changes over baseline, to avoid confusion with changes in the penile position that resulted from motion of the man during sleep.

For statistical analysis we used a two-tailed student's t-test for means, and a Pearson correlation coefficient.

Results

A total of 25 patients suffering from ED and with a mean age of 42 years (22-66 year) were included in the study. The data concerning the study participants are mentioned in Table I.

NPTR and nocturnal electrobioimpedance measurements were obtained during the same night for a mean of 446 minutes (310 to 590 minutes).

The mean number of erections/night as determined by NEVA® and RigiScan® did not differ significantly, (2.80±0.34 vs 2.76±0.31 respectively). A Pearson correlation of 88% was observed.

Depending on the assessment method used the mean duration of the erection was significantly different ($p<0.05$). NEVA® registered mean durations of 30.66±1.92 minutes, whereas erections appeared to be shorter (25.63±1.62 minutes) when assessed by RigiScan®. Pearson correlation amounted in this case to 55.5%.

All grade III erections (70-100% rigidity) on RigiScan® corresponded to more than 200% volume change over baseline with NEVA® (mean 275.62±31.18%). Even grade II erections (40-70% rigidity) corresponded in 20% of the cases to erections with more than 200% volume change over baseline. When all patients with a grade II erection as determined by RigiScan® were considered together, their mean increase in penile volume during erection amounted to 187.61±19.97%.

In 21 patients (84%), an analysis of the NEVA® data according to Knoll and Billups [6] algorithm, allowed to diagnose the exact origin of ED. In 3 patients (12%) the diagnosis of a mild arterial insufficiency was made but the final diagnosis after complete work-up was ED of psychologic origin. The penile duplex Doppler examination revealed a mild arterial insufficiency in 1 patient although a normal NEVA® was obtained.

Discussion

The monitoring of sleep-associated erections for the evaluation of impotence has been in existence

Table I. Pertinent features of patients, duration of nocturnal assessment by means of NEVA, and diagnoses

Patient number	Age (years)	Registration time (min)	NEVA diagnosis	Final diagnosis (at completion of work-up)
1	49	450	Normal	Normal
2	49	580	Venous	Venous
3	60	360	Arterial	Arterial
4	64	480	Normal	Arterial
5	57	590	Arterial	Arterial
6	47	440	Normal	Normal
7	47	540	Normal	Normal
8	30	480	Arterial	Arterial
9	36	420	Arterial	Arterial
10	26	480	Arterial	Normal
11	38	380	Arterial	Normal
12	36	440	Normal	Normal
13	26	470	Normal	Normal
14	27	500	Normal	Normal
15	28	530	Normal	Normal
16	26	540	Normal	Normal
17	54	390	Arterial	Arterial
18	61	360	Arterial	Normal
19	40	410	Arterial	Arterial
20	46	390	Arterial	Arterial
21	45	380	Normal	Normal
22	40	480	Normal	Normal
23	38	310	Normal	Normal
24	32	360	Normal	Normal
25	48	390	Normal	Normal

for years. The quality of nocturnal erections has been traditionally used to differentiate psychogenic from organic impotence. In formal nocturnal penile tumescence testing, penile circumference changes were monitored at its base and at the tip with mercury strain gauges during three consecutive nights spent in a specialised sleep facility. In addition, electroencephalographic, electro-oculographic, and electromyographic activities were simultaneously recorded, because the quality and quantity of sleep affect the erectile activity. During the study, the patients were awakened in the midst of an erectile episode. The axial rigidity of the erection was determined by assessing the resistance of the penis to buckling when applying a known weight against the glans. Such measurements were necessary because normal penile circumferential changes may occur in the absence of adequate penile rigidity. The inconvenience to the patient of sleep laboratory testing has led to the development of portable devices for a nocturnal penile tumescence testing at home. Devices utilizing strain gauges to measure changes in penile circumference to detect the presence of nocturnal erections did not record penile rigidity. The RigiScan® device has been designed to measure penile rigidity during nocturnal monitoring at home but it fails to document the sleep quality. These testing methods corroborated results obtained with other diagnostic methods and identified the organic or the psychogenic origin of impotence in 68% of the cases [11].

Numerous false-positive and false-negative results occur with a sleep-associated erection recording. Nevertheless, the test should be performed when doubt persists as to whether the patient's impotence is due primarily to a psychogenic or an organic cause. RigiScan® recording failed to differentiate between arteriogenic, venogenic, and neurogenic impotence [8]. This testing method is neither specific nor sensitive enough to be utilized as a single modality of diagnostic evaluation. Its results should be confronted with other aspects of

the diagnostic work-up. Furthermore, the device measures radial rigidity by measuring the rigidity of the circumference of the penis, which gives no information on the much more important axial rigidity, and whether penetration can be achieved.

Knoll and Abrams introduced the NEVA® device [6]. With this latter penile length, cross-sectional area and volume of the penis are recorded during sleep, at intervals of one second. From these variables, the number and duration of the erectile events and the percentage of volume increase as compared to the resting, flaccid state can be determined. The changes in blood volume in the penis during an erection were evaluated by a simultaneous duplex Doppler examination. The NEVA® device is small and comfortable to wear. Because of its small size and non-constricting electrodes attached to the penis, the NEVA® system was well accepted by the men participating in our study. All of them stated that the device is easy to use and comfortable enough not to interfere with sleep. Knoll and Abrams stated that an analysis of all sessions showed that all nighttime recordings are comparable, which argues against the first night effect [6]. Nevertheless, we performed the study only the last night of RigiScan® recordings to avoid the first night effect.

Two questions can be answered positively. Firstly, NEVA® gives information on nocturnal erections which is comparable to that obtained with the RigiScan®. A correlation of 88% in erectile events between NEVA® and RigiScan® demonstrates that the same erectile events are recorded. The non-continuous registration by the RigiScan® and the second by second recording of the NEVA® can explain the statistically significant difference in duration of erections. All grade III erections on RigiScan® corresponded with more than 200% change over baseline. Also 20% of grade II erections were classified as normal according to the Knoll and Billups algorithm [6]. Then we address the second question: The registration of the rigidity during nocturnal testing is of paramount importance for prediction of a successful sexual intercourse. RigiScan® measures radial rigidity, NEVA® measures axial rigidity. The latter seems more important because the possibility of vaginal penetration and pursued sexual intercourse is the only point of interest to the patient. NEVA® seems more reliable for the assessment of the quality of erections and for the prediction of the potential to achieve a successful sexual intercourse.

Furthermore, the NEVA® device has a good diagnostic accuracy. In 84% of the cases NEVA® analysis provided the correct diagnosis of ED. Pathognomonic patterns of arteriogenic and venogenic impotence exist. In three patients the analysis of the data showed a mild arterial insufficiency while the overall results of the diagnostic work-up were indicative of a psychogenic ED. Some illnesses, certain sleep disorders, various medications and various emotional statuses, including anxiety, depression and suppressed sexual desire, adversely influence nocturnal penile erections [12-13]. The efficacy of NEVA® in establishing the overall diagnosis of ED is not surprising. Knoll and Abrams calibrated NEVA® using duplex Doppler ultrasound measurements [7]. In our study, the duplex Doppler measurement was also the principal diagnostic tool.

In the future one should determine the normal values for a wide range of ages in men with no history of ED. Although anatomical variations in penile length, cross-sectional area and volume are likely, it should be possible to define normal ranges for the number and duration of erectile events, as well as for the fractional changes in volume over baseline during these events.

Conclusions

The present study demonstrates that electrobioimpedance registration by means of a NEVA® device correlates well with a conventional penile tumescence testing. NEVA® measures changes in axial rigidity, which is a more important feature than radial rigidity for qualifying erections. Futhermore NEVA® analysis seems to be an important and easy tool for predicting the etiology of ED.

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