COMPARISON OF RESULTS OF NOCTURNAL PENILE TUMESCENCE AND RIGIDITY IN A SLEEP LABORATORY VERSUS A PORTABLE HOME MONITOR

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ABSTRACT

Objectives. To validate the results of the home penile tumescence monitor versus the sleep laboratory studies of erectile function.

Methods. We used both methods to study 18 episodes of rigidity and 19 episodes of tumescence in 10 subjects with erectile dysfunction before and after the use of an experimental vasodilating medication.

Results. The tumescence measurement in the sleep laboratory compared favorably with the changes in tumescence with the RigiScan portable home monitor: at the base ($r = 0.70; P < 0.001$) and at the tip ($r = 0.84; P < 0.001$). In measuring rigidity, the buckling pressure in the sleep laboratory compared favorably with the RigiScan measurements of percent average rigidity at the base ($r = 0.56; P = 0.017$), at the tip ($r = 0.62; P = 0.006$), and mean rigidity of the base and tip ($r = 0.64; P = 0.004$). In a comparison of the buckling pressure with the new RigiScan Plus quantitative program, there was good correlation with the rigidity activity units at the base ($r = 0.70; P = 0.001$) and at the tip ($r = 0.72; P < 0.001$). A clinical estimate of penetrable rigidity correlates with the RigiScan base rigidity of 55% to 60% and tip rigidity of about 50%.


In the past, it has often been difficult to distinguish between organic and psychologic causes of erectile dysfunction. Although it had been shown that penile erections occurred regularly in men during the night, Fisher et al. related these episodes to rapid eye movement (REM) sleep. Karacan et al. noted that 80% of nocturnal erections occurred during REM sleep. It was not long until regular monitoring of erections during sleep in a sleep laboratory was performed in the evaluation of erectile dysfunction, especially to differentiate between organic and psychogenic causes. Tumescence was measured with mercury strain gauges. Rigidity was measured separately because a number of patients were found to have normal tumescence but poor rigidity. Penile rigidity was thought to be best measured axially with a tonometer because axial rigidity was thought to correlate most accurately with the ability to achieve vaginal penetration. This device measures the grams of force required to produce penile buckling. It was often difficult, however, to distinguish organic from psychologic disease.

One possible area of difficulty was that measurable parameters decreased with age. Sleep laboratory measurements found that the frequency of erectile episodes and their duration tended to decrease with age, but the degree of circumferential increases does not change. The quantitative RigiScan software (Dacomed Corporation, Minneapolis, Minn) has also recently shown that there was a tendency for shorter event duration with age but not for percent event rigidity measurements nor for the area of rigidity measurements. Even with these differences, sleep-related penile studies, to this day, are thought to be a valid and objective means of assessing erectile function.

Clinicians believed that patients would be more at ease being studied in the privacy of their own home rather than in the potentially embarrassing environment of a sleep laboratory. Therefore, portable
TABLE I. Demographic data of the study subjects

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yrs)</th>
<th>Impotence</th>
<th>Medications</th>
<th>Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>64</td>
<td>P</td>
<td>None</td>
<td>Alcohol excess</td>
</tr>
<tr>
<td>2</td>
<td>65</td>
<td>O</td>
<td>None</td>
<td>ED</td>
</tr>
<tr>
<td>3</td>
<td>6/1</td>
<td>O</td>
<td>None</td>
<td>ED</td>
</tr>
<tr>
<td>4</td>
<td>58</td>
<td>O</td>
<td>Glyburide, verapamil, hydrochlorothiazide</td>
<td>Type II diabetes mellitus, hypertension, alcohol excess</td>
</tr>
<tr>
<td>5</td>
<td>59</td>
<td>O</td>
<td>None</td>
<td>Tobacco, wife ill</td>
</tr>
<tr>
<td>6</td>
<td>50</td>
<td>O</td>
<td>Testosterone injections</td>
<td>Hypogonadism, Peyronie’s disease</td>
</tr>
<tr>
<td>7</td>
<td>52</td>
<td>O</td>
<td>Insulin</td>
<td>Type II diabetes mellitus</td>
</tr>
<tr>
<td>8</td>
<td>49</td>
<td>O</td>
<td>Insulin</td>
<td>Type II diabetes mellitus</td>
</tr>
<tr>
<td>9</td>
<td>67</td>
<td>O</td>
<td>None</td>
<td>Alcohol excess</td>
</tr>
<tr>
<td>10</td>
<td>57</td>
<td>O</td>
<td>Insulin, glyburide</td>
<td>Type II diabetes mellitus</td>
</tr>
</tbody>
</table>

Key: ED = erectile dysfunction only; O = organic; P = psychologic.

strain-gauge monitors were tried and found to correlate fairly well with tumescence measured in the sleep laboratory setting. The use of the monitor was somewhat cumbersome, and rigidity was not measured. Home screening by a simpler means was attempted with snap gauges. The most commonly used monitor has a Velcro fastener and several plastic strips that break at varying tensile strengths. Although it was cost-effective, subsequent testing revealed significant discrepancies between the results of the snap gauge and formal nocturnal penile tumescence testing. It also did not produce any direct information on rigidity.

In 1985, a portable home monitor was developed that could continuously and simultaneously monitor tumescence as well as rigidity and store the information on a computer chip that could later be downloaded and converted to a paper tracing. The technical aspects have been reviewed in detail. The RigiScan monitor (Dacomed) has been used successfully to separate psychogenic from organic causes of organic failure in a clinical setting. The monitor has continued to be validated as a diagnostic tool that can verify biogenic impotence. Recently, RigiScan monitoring has been shown to be superior to a history and physical examination alone in diagnosing organic erectile dysfunction.

Although the RigiScan monitor seems to be a valid clinical tool, debate continues concerning the superiority of nocturnal evaluation in a sleep laboratory. Allen et al. stated that penile rigidity, as measured by the RigiScan home monitor, did not correlate with penile buckling pressure over 450 g of buckling force. We disagreed and decided to study both techniques on men with organic erectile dysfunction during a clinical trial.

MATERIAL AND METHODS

Ten men aged 49 to 71 years (median 58) were studied (Table I). The men were part of a clinical trial using a topical vasodilating cream whose purpose was to enhance penile tumescence and rigidity. The men were studied in the sleep laboratory before and/or after applying the cream to the shaft of the penis twice a day for 6 weeks, and they agreed to use the RigiScan home monitor as well. Some used the monitor the day before the sleep laboratory session and some the day after; these were equally divided. Nineteen episodes of nocturnal tumescence and 18 episodes of rigidity were compared; 2 nights of each technique were completed. The numbers of episodes measured in the sleep laboratory ranged from 2 to 7 per night (mean 4.35); the number of episodes as measured with the RigiScan monitor ranged from 1 to 5 per night (mean 3.05). The definition of a valid tumescence episode with the RigiScan monitor is a reading that rises 20% above baseline for a minimum of 3 minutes followed by at least 5 minutes back to baseline. In the sleep laboratory, the minimum circumference change to validate an episode was a 2-mm increase above the baseline measurement. The definition of “normal” erectile rigidity in the sleep laboratory, as measured by a pressure tonometer, was a minimum of 500 g of buckling pressure. Normal erectile capacity, as measured by the RigiScan monitor, was defined as 60% rigidity at the base and 50% rigidity at the tip, as was previously defined. These numbers refer to the percentage of firmness relative to a theoretical maximum calibrated with a semirigid rubber cylinder. The RigiScan portable home monitor measured percent average rigidity at the base of the penis, percent average rigidity at the tip of the penis, and percent mean average rigidity, using a standard quantitative analysis software package (Dacomed). We also used a new quantitative software package, as found in RigiScan Plus. It measures the area under the curve of a rigidity episode in units called rigidity activity units (RAU). It represents the product of the minutes spent at a given rigidity level and the rigidity level expressed in decimal form. Rigidity was measured as buckling pressure —by the pressure tonometer in the sleep laboratory—when the technician saw an acceptable tumescent episode as measured in continuous real time by mercury strain gauges.

The statistical analysis of the data was performed using simple linear regression and the Pearson product-moment correlation coefficient.

RESULTS

A high degree of correlation was observed between tumescence measured in the sleep laboratory (maximum circumference over baseline) and the portable home monitor (best episode of change
TABLE II. Tumescence measurements compared

<table>
<thead>
<tr>
<th>Tumescence Episodes</th>
<th>Sleep Laboratory (Maximum Circumference)</th>
<th>RigiScan (Change in Tumescence)</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 19</td>
<td>Base</td>
<td>Base</td>
<td>$r = 0.70; P &lt; 0.001$</td>
</tr>
<tr>
<td>n = 19</td>
<td>Tip</td>
<td>Tip</td>
<td>$r = 0.84; P &lt; 0.001$</td>
</tr>
</tbody>
</table>

TABLE III. Rigidity measurements compared

<table>
<thead>
<tr>
<th>Rigidity Episodes</th>
<th>Sleep Laboratory</th>
<th>RigiScan</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 18</td>
<td>Buckling pressure</td>
<td>% Average rigidity base</td>
<td>$r = 0.56; P = 0.017$</td>
</tr>
<tr>
<td>n = 18</td>
<td>Buckling pressure</td>
<td>% Average rigidity tip</td>
<td>$r = 0.62; P = 0.006$</td>
</tr>
<tr>
<td>n = 18</td>
<td>Buckling pressure</td>
<td>% Average rigidity mean</td>
<td>$r = 0.64; P = 0.004$</td>
</tr>
<tr>
<td>n = 18</td>
<td>Buckling pressure</td>
<td>RAU (base)</td>
<td>$r = 0.70; P = 0.001$</td>
</tr>
<tr>
<td>n = 18</td>
<td>Buckling pressure</td>
<td>RAU (tip)</td>
<td>$r = 0.72; P &lt; 0.001$</td>
</tr>
</tbody>
</table>

Key: RAU = rigidity activity units (measure of amplitude of rigidity over time $i = area$).

FIGURE 1. (A) The RigiScan tracing shows abnormal findings that correlate with an abnormal buckling pressure of 200 g. (B) A RigiScan tracing shows normal findings corresponding to a normal rigidity reading of 500 g by measurement of buckling pressure.

of tumescence over baseline) both at the base ($P < 0.001$) and at the tip ($P < 0.001$) of the penis (Table II). Both techniques agreed with equal sensitivity as to whether the readings were normal or abnormal. The buckling pressure, as measured in the sleep laboratory as the best reading noted in 2 nights, correlated well with the percent average rigidity of the base ($P = 0.017$), with the tip ($P = 0.006$), and even the mean of the base and tip ($P = 0.004$; Table III). The buckling pressure correlated even better with the RAUs, measured both at the base ($P = 0.001$) and at the tip ($P < 0.001$). Both were recorded as the best erectile episode during the 2 nights. An abnormally low buckling pressure of 200 g with its corresponding abnormal RigiScan graph is seen in Figure 1A, and a normal buckling pressure of 500 g with its equally normal RigiScan graph is seen in Figure 1B.

COMMENT

Although it is only one aspect of the total evaluation of erectile dysfunction, nocturnal penile testing is thought to be an integral part of this investigation. It has become part of our clinical armamentarium to differentiate between organic and psychogenic causes of erectile dysfunction. Besides nocturnal monitoring, portable monitors have been used to evaluate the response to visual sexual stimulation with and without concurrent penile injections of papaverine. They have also been found helpful in anticipating the dose of medication needed for intracavernous injection therapy or to diagnose venous leakage. This study has shown that the RigiScan portable home monitor gives comparable readings to those obtained in the sleep laboratory setting. Tumes-
ience readings with the loops of the portable monitor were similar to those of the mercury strain gauges of the sleep laboratory monitor. Rigidity measurements with the portable monitor's internal monitoring system were comparable to the sleep laboratory's use of buckling pressure, as measured by a spring tonometer.

This brings up several points: As mentioned earlier, nocturnal erections have been shown to change quantitatively as a man ages, and this has been shown in the sleep laboratory as well as with a portable home monitor. The amount of buckling pressure, as measured in the sleep laboratory, is a matter of debate; although the minimal normal pressure varies between 450 and 600 g, the pressure may vary according to the size of the vagina and the degree of lubrication. On the other hand, measurement of rigidity by the portable monitor was initially underestimated and, similar to buckling pressure, has varied somewhat in the literature. Our definition of minimal penis rigidity necessary for vaginal penetration (that is, 60% rigidity at the base, 50% rigidity at the tip, and episodes of 10 minutes' minimal duration) is based on clinical correlation in more than 1000 patients studied. Although parameters of nocturnal penile activity decrease with age, sexual function has been shown to be normal. Part of the confusion is that some of the earlier normal parameters only were obtained in a younger male population. Ogrinc and Linet monitored intracavernosal injections of alprostadil with the RigiScan monitor and compared the readings with the clinical opinion of an erection firm enough for vaginal penetration. When 60% or greater was used instead of 70% in the RigiScan for degree of rigidity, the sensitivity rose from 53.8% to 70.8%, indicating the standard criterion of 70% is overestimated.

Licht et al. compared the sleep laboratory measurements with the RigiScan measurements. Even if one might question the technique of using both the strain-gauge leads and the RigiScan leads in the same evening, they found, at least at the base of the penis, that the rigidity measurements were comparable. Further, with added analysis, they believed that base rigidity of 55% was probably normal. This is close to our clinical estimate of 60%.

We also compared the earlier quantitative analysis software for the RigiScan portable home monitor unit with the newer RigiScan Plus software package. The correlation was even better when buckling pressure was compared with the newer software. The rigidity is reported as RAUs, which measure integrated time-intensity area measurements of rigidity.

One valid observation is that the sleep laboratory offers simultaneous measurement of penile activity and the various stages of sleep. Most erections occur with REM sleep, and these cycles can vary with age. Apart from severe mental or physical illness and medications that act on the central nervous system, the majority of sleep disorders that may affect REM sleep would be sleep apnea or nocturnal myoclonus. Questions as to whether there is a decrease in breathing during sleep or constant jerking of the extremities are asked. If sleep disorders are present, the traditional sleep laboratory examination is preferred. An alternative we have used occasionally has been to monitor REM sleep in the sleep laboratory while the patient concurrently uses the RigiScan monitor. This study may have the benefit of not creating adrenalin-producing anxiety changes in the recordings if the patient awakens during the penile manipulation necessary to obtain penile buckling pressure.

In conclusion, nocturnal penile tumescence and rigidity can be measured just as accurately with a portable home monitor as with the more cumbersome and more expensive analyses performed in a sleep laboratory. The portable monitor has a definite place in the clinical evaluation of erectile dysfunction, especially to help differentiate between an organic and a psychogenic cause.

REFERENCES

11. Kropman RF, Tegelaar RJ, Zwinderman AH, Lycklama A, Nijeholt AA, Meinhardt W, and Zwartendijk J: Analysis of


