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Real-time Penile Tumescence and Rigidity Monitoring: A Pilot Study in Healthy, Potent Men

Henry Gottsch, Claire C Yang
Department of Urology, University of Washington, Seattle, Washington, USA
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ABSTRACT

INTRODUCTION: RigiScan™ penile monitoring can be used in the provocative (real-time) setting. However, normative data are limited. The goals of the present prospective study were to (1) generate preliminary data on the range of responses of real-time penile monitoring during audio-visual sexual stimuli (AVSS) in healthy, potent men, and (2) determine if there was an association between real-time erectile rigidity in response to AVSS and self-reported measures of erectile function.

METHODS: The participants were 25 potent men. Their ages ranged from 19-58 years. They were arbitrarily divided into younger (< 40 years) and older (≥ 40 years) groups for outcome measure comparisons. An International Index of Erectile Function (IIEF) erectile domain score was obtained. RigiScan™ monitoring was used to record erectile responses of penile tumescence and rigidity to AVSS. A qualified erectile event was defined as penile rigidity > 60% for 3 or more minutes.

RESULTS: The mean IIEF score for all participants was 29.3, with no significant difference between the younger or older groups (P = .95). Three men had no measureable erectile activity in response to the AVSS. For the remaining 22 men, measurable erectile activity ranged from 3-20.5 minutes. The mean time of measurable rigidity was 12.0 minutes and 11.9 minutes for the younger and older groups, respectively. Age and total erection time had a weak negative correlation (Pearson r = -.31). Ten participants (40%) achieved a qualified event of 60% rigidity. A total of 7 of the 15 participants in the younger group and 3 of the 10 participants in the older group had a qualified event. There was no significant difference in IIEF scores between participants with and without qualified events (P = .35).

CONCLUSIONS: Preliminary results indicate that real-time penile tumescence and rigidity monitoring in potent, healthy males during AVSS is highly variable and not necessarily corroborated by IIEF scores. This variability limits the utility of provocative mode RigiScan™ for determining potency for clinical purposes. A 60% rigidity criteria for a qualified event may underestimate potency. However, the RigiScan™ may still be effective for studies of erectile physiology.

KEYWORDS: Penis; Rigidity; Monitoring; Potent; Men

CORRESPONDENCE: Henry Gottsch, MD, University of Washington, Dept of Urology, 1959 NE Pacific St, BX 356510, Seattle, WA 98195-6510, USA (henryg@uw.edu).

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Abbreviations and Acronyms

AVSS = audio-visual sexual stimuli
IIEF = International Index of Erectile Function
NPTR = nocturnal penile tumescence and rigidity
VSS = visual sexual stimuli

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INTRODUCTION

Penile measurements during the erectile response, as described by Kaneko and Bradley [1], changed the evaluation of male sexual function. Use of the RigiScan™ rigidity assessment system (Timm Medical Technologies, Eden Prairie, MN, USA) improved the quality of data from nocturnal penile measurements. Subsequently, much work has been done to characterize nocturnal erections and their relationship with volitional erectile function. The RigiScan™ is capable of real-time penile monitoring in the clinical or laboratory setting, but normative values in healthy potent males are underreported.

Real-time monitoring may be helpful in defining physiological changes that occur during erection in response to different stimuli. Previous studies with real-time erectile monitoring have induced erections through pharmacologic intervention, tactile stimulation, or visual sexual stimulation (VSS), either as single agents or in combination [2-5]. The primary measurement of the RigiScan™ is penile rigidity, which is reported as a percentage calibrated to the rigidity of a steel rod (set at 100%). A rigidity measurement of 70% was put forth by the manufacturer as adequate for intromission, based on nocturnal data [1]. In the real-time setting, others have proposed a criteria of 60% rigidity as a more appropriate normative threshold [4]. There has not been a study prospectively examining real-time rigidity monitoring in healthy, potent men.

The most easily administered and commonly used measure of erectile function is a patient-completed questionnaire. The International Index of Erectile Function (IIEF) is a widely accepted, validated example of such an instrument [6]. The erectile domain of the IIEF allows the clinician or researcher to numerically stratify participants based on degree of function. However, in sexual medicine investigations, subjective reporting on a questionnaire may not necessarily corroborate with data recorded in physiological measurements [7]. Previous authors have examined the relationship between nocturnal penile tumescence and rigidity (NPTR) measurements and IIEF responses, but not with real-time monitoring [8].

Given the paucity of data on real-time penile monitoring, the goals of the current study were to: (1) generate preliminary data on the range of responses of real-time penile monitoring during audio-visual sexual stimuli (AVSS) in healthy, potent men; and (2) determine if there was an association between real-time erectile rigidity in response to AVSS and self-reported measures of erectile function.

METHODS

Participants

The participants were 25 healthy, potent, sexually active men. Their ages ranged from 19-58 years old. All participants underwent a physical examination and health assessment prior to the study procedure, to confirm the absence of disease and risk factors for erectile dysfunction.

For comparative purposes, the participants were arbitrarily divided into 2 age groups. The younger group was ≤ 39 years old (N=15); the older group was ≥ 40 years old (N=10). The mean ages were 22.6 years and 48.4 years for the younger and older groups, respectively.

Procedures

The study was approved by the University of Washington Human Subjects Review Committee. All participants provided informed consent.

Each participant completed a self-reported assessment of erectile function using the erectile domain section of the IIEF. The participant was then asked to lie in a supine position on a comfortable examination table. The examination room was dimly lit for comfort. An audiovisual headset was placed on the participant's head and adjusted to a comfortable volume.

A RigiScan™ device was used to record the data. It was set in the provocative (real-time) mode. Data were gathered over a 35-minute session, with penile tumescence and rigidity measurements recorded via 2 contracting looped cables. One cable was placed at the base of the penis; the other cable was placed at the tip of the penis, just proximal to the corona. Baseline measurements were recorded for 15 minutes while the participant lay quietly, without any input through the headset.

After baseline recordings were obtained, a preselected 20-minute erotic video was shown to the participant through the headset. Participants were specifically instructed to avoid manual genital stimulation.

RigiScan™ monitoring was done throughout the video. The RigiScan™ software reports data as a continous measurement (Figure 1). A qualified erectile event is defined as a >20% increase in baseline tumesence sustained for at least 3 minutes, but the qualifying percentage of rigidity must be predetermined by the investigator. The rigidity was set at 60% for this study. Penile rigidity of 60-70% is considered adequate for vaginal intercourse.

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Figure 1. Data Output From a Real-time, Provocative RigiScan™ Monitoring Session.
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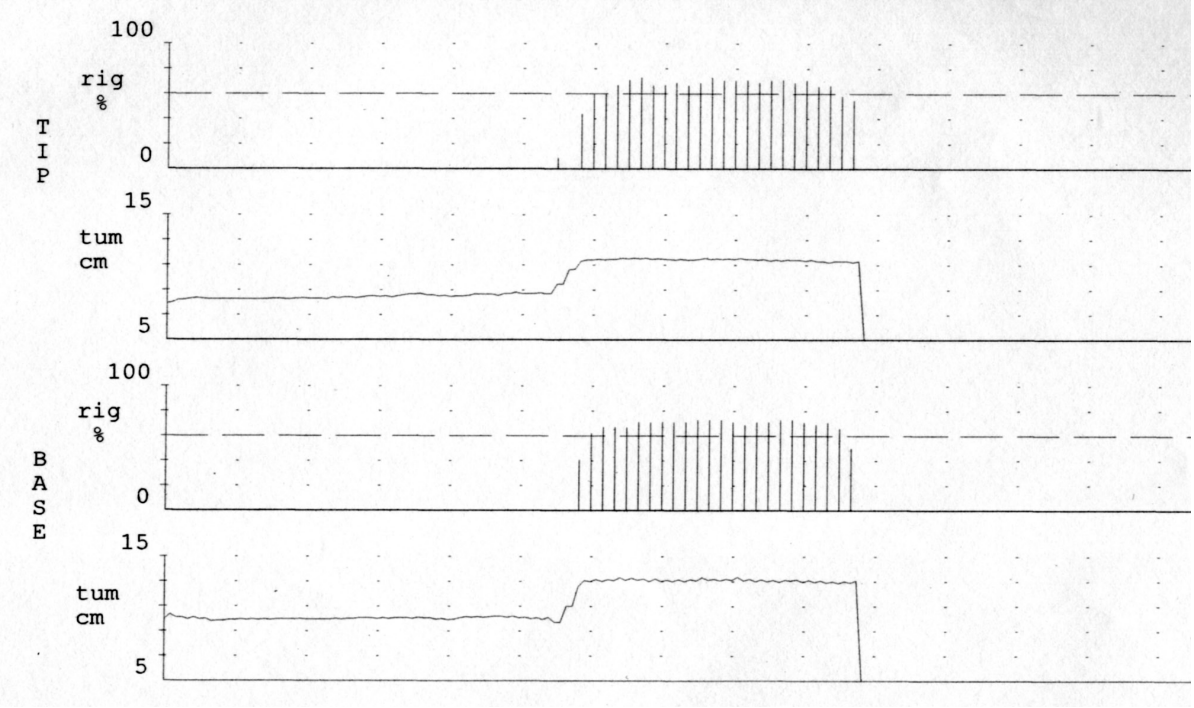

Rigidity and tumescence for penile tip and base are presented. Each vertical bar represents a rigidity measurement (% of a steel bar) taken every 30 seconds.
Hatched horizontal line marks = 60% rigidity. Screen width = 1 hour.
Abbreviations: tum, tumescence; rig, rigidity; cm, centimeter.

Data Analysis

Outcome measures for the younger and older age groups were compared using the two-tailed *t* test. Statistical significance was defined as $P < .05$. Pearson's correlation coefficient was used to examine the relationship between total erection time and age. All analyses were calculated using Stata software, Version 8 (Stata Inc, College Station, TX, USA).

RESULTS

The mean erectile domain IIEF score for all participants was 29.3, out of a possible 30 (range 26-30). There was no signficant difference in mean IIEF scores between the younger and older groups ($P = .95$).

Of the 25 participants, all but 3 had measurable erectile activity. The 3 participants without erectile activity were in the older age group. The mean rigidity measurement was 50% (range, 0-84%).

Of those with measurable erectile activity, the mean time of the erectile event was 11 minutes (range, 3-20.5 minutes). No significant differences were noted between tip and base rigidity or tumescence; therefore, tip data are presented for simplicity. The mean time of measurable tip rigidity was 12.0 minutes and 11.9 minutes for the younger and older groups, respectively. There was no significant difference in the mean duration of rigidity between the younger and older groups ($P = .21$).

The total time of erection versus age for all participants is presented as a scatter plot in Figure 2. These variables had a weak, negative correlation (Pearson $r = -0.31$).

Ten participants (40%) were able to achieve 60% rigidity in a qualified erectile event. There was no significant difference in the IIEF erectile domain scores of those who had a qualified erectile event and those who did not ($P = .35$). A total of 7 of the 15 participants in the younger group and 3 of the 10 participants in the older group had a qualified event.

Figure 1. Age Versus Total Erection Time (in Minutes) for All Participants.
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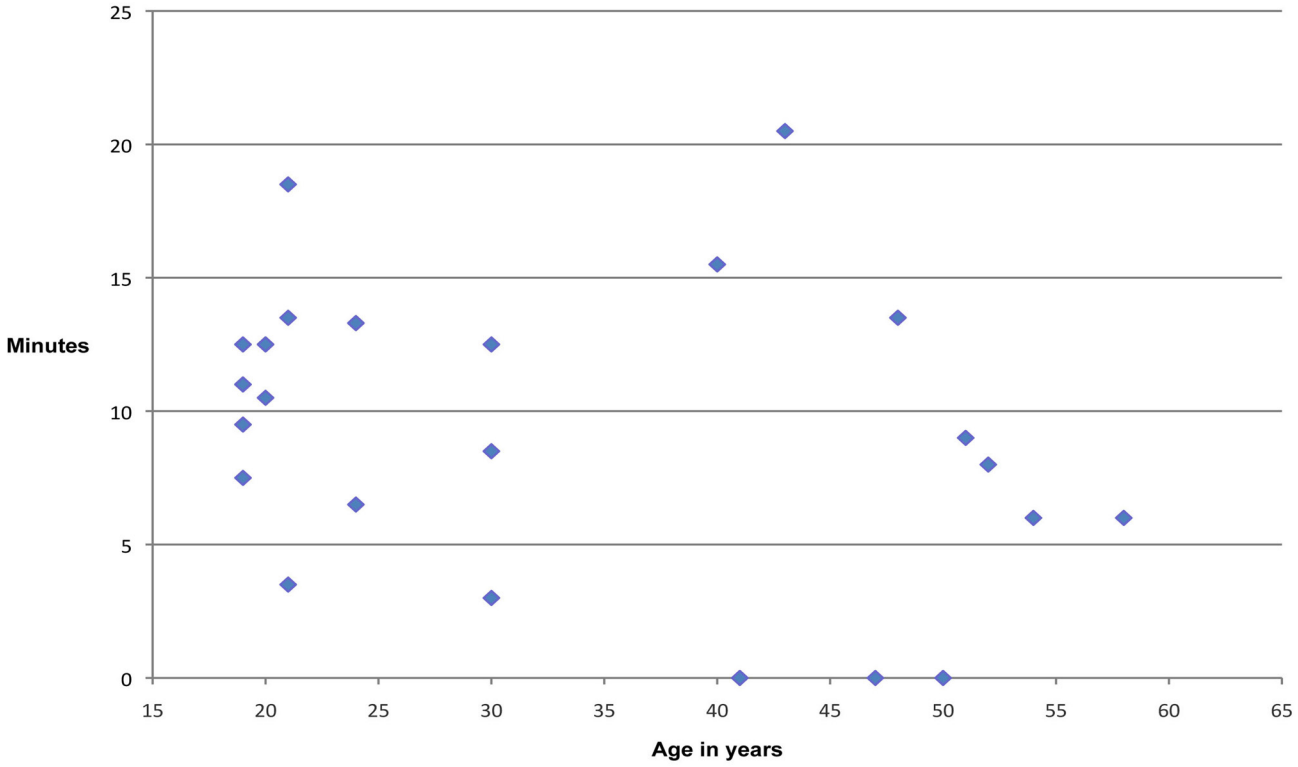

DISCUSSION

In this small group of healthy men who self-reported intact erectile function, there was a wide range of erectile capacity in response to AVSS during real-time penile tumescence and rigidity monitoring. IIEF erectile domain scores ranged from 26-30 of 30 possible points, indicating no perceived erectile dysfunction. Maximum penile rigidity, which is the primary determinant of erectile function, ranged from 0% to > 80% in the laboratory setting, and only 40% of participants were capable of a qualified 60% rigidity erectile event. Thus, there does not appear to be a consistently reliable association between self-reported erectile function and laboratory measurements of spontaneous erectile capacity. Furthermore, the variability of real-time rigidity measurements in the healthy male's response to AVSS makes it difficult to select criteria to define potency.

In healthy potent men, measures of normal erectile function are underreported. The present is the first known prospective study that specifically tests the range of real-time erectile responses in healthy, potent participants using penile monitoring. However, there are several studies with comparable methods where healthy, potent participants were used as a control group. Kim et al [10] reported that potent control group participants undergoing multiple sessions of real-time penile monitoring with VSS had peak rigidity ranging from 13%-30%. Their data contrast with the rigidity scores presented by Martins and Reis [2], who showed that 85% of control group participants undergoing VSS were capable of achieving an erection that was >60% rigid. Martins and Reis assessed adequacy for vaginal penetration or intercourse by self-reported evaluation and clinician assessment. However, they did not report the age of the controls. The present data suggest that age may have an impact on real-time penile measurements. If the cohort in the Martins and Reis study was young, age may have accounted for the larger percentage of participants with qualified erectile events. Thus, there appears to be a wide range of responses within the literature. This variation matches the findings of the present investigation.

Rigidity criteria for real-time penile monitoring are based on nocturnal monitoring values deemed adequate for intromission. The use of 60% versus 70% rigidity as criteria for a qualified erectile event was directly addressed in previous

work regarding real-time monitoring by pharmacologically-induced erections. The sensitivity for potency improved from 47.6% to 64.9% by lowering the threshold [4]. Hatzichristou and colleagues [11] performed nocturnal testing in potent men and found that 52% of participants had a qualified event of 60% rigidity. The results of the present study suggest that 60% rigidity may not be an appropriate normative criterion for provocative monitoring. Furthermore, there is no clear threshold in the present results that would suggest a different recommended criterion.

A second preliminary finding from the present study is age-associated rigidity. The correlation of age and time of erection was negative and weak, and it must be interpreted with caution because of the small number of participants in each group. However, the percentage of older participants able to achieve a qualified erection with 60% rigidity was less than in the younger group, and 3 of the older participants did not demonstrate any erectile activity. Rowland et al [12] demonstrated that there is a decrease in penile tumescence parameters in the aging male. Another explanation for the comparative decrease in penile measurements is that the older participants may not have been as affected by the erotic material presented, although all claimed to find the material sexually arousing.

Age is not the only factor that can impact the measurement of erectile activity in the laboratory. NPTR monitoring was developed, in part, to remove the erectile function evaluation from the clinic or research laboratory and minimize the inhibitory effects of the laboratory environment. Based on their work, Djamilian and colleagues [13] suggested medicating participants prior to VSS to decrease the anti-erectile effects of anxiety and increase sympathetic activity. The current study design does not account for the contributions of psychological inhibition on erectile function, and this factor may be a primary reason for the high variability of responses. Additionally, multiple viewings of erotic material can decrease erectile response to VSS [10]. In an attempt to minimize this effect, the present participants were tested one time. Provocative rigidity monitoring will always have limits as a measure of potency, because the Rigiscan™ is intrusive, and functional testing does not include the act of intercourse. It may be best to utilize AVSS and real-time rigidity monitoring to measure erectile physiology and not sexual potency.

The correlation between subjective IIEF responses and objective penile measurements should be interpreted with caution, because these measures may yield conflicting results [8,9]. Questionnaires measure men's perceptions of erectile function, and penile measurements record anatomical changes. Both are subject to fluctuation, and the range of physiological factors that allows adequate erectile function appears to be highly variable for individuals [8]. All 25 of the present participants reported that they were potent, which was corroborated by their IIEF scores. Most of these self-reported potent men had some measurable erectile activity. Real-time penile tumescence and rigidity monitoring in the clinical setting appears to be of limited benefit, given the response variability. However, in physiologic investigations any erectile activity with real-time monitoring may be a valid response, so threshold rigidity is not always an appropriate metric. An additional problem with comparing the 2 types of assessments is that several of the questions on the IIEF specifically refer to erectile function during intercourse, whereas measurements during provocative RigiScan™ are during AVSS only.

CONCLUSIONS

Preliminary results of real-time penile tumescence and rigidity monitoring in potent, healthy males during VSS are highly variable and not corroborated by IIEF erectile domain scores. This variability limits the utility of the provocative-mode RigiScan™ for clinical purposes. RigiScan™ 60% threshold rigidity criteria may underestimate potency in the real-time setting. However, the technique of provocative monitoring may still be valid for studies of erectile physiology where threshold rigidity is not applicable.

Conflict of Interest: none declared

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