
Viberect penile vibratory stimulation system: evaluation of its erectogenic efficacy

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SEGAL RL, TAJKARIMI K, BURNETT AL. Viberect penile vibratory stimulation system: evaluation of its erectogenic efficacy. *Can J Urol* 2013;20(4):0000-0000.

Introduction: Current non-surgical strategies employed to treat erectile dysfunction (ED) target the vascular component of erection physiology. The Viberect handheld device (Reflexonic, LLC, Chambersburg, PA, USA) is a new FDA-cleared ED treatment, which exploits vibratory stimulation of genital afferent nerves for provoking erections. The aim of this study was to evaluate the clinical feasibility of the Viberect device for the achievement of penile erection and rigidity.

Materials and methods: Subjects for this study were five healthy men (mean age 26.4 years) with normal erectile function as measured by responses to the IIEF-EF. The Viberect treatment at 75 Hz with ventral stimulation was initiated without any external visual sexual stimulation. Both objective Rigiscan measurements of rigidity and subjective Erection Hardness Score (EHS) responses were recorded and correlated. Tolerant and safety were monitored.

Results: Rigiscan demonstrated that 4/5 patients achieved tumescence episodes beyond 60% total rigidity (considered the minimum required to achieve a non-buckling erection capable of vaginal intromission). According to EHS, the Viberect treatment yielded scores of 4/4 (penis is completely hard and fully rigid) in 2 patients, 3/4 (penis hard enough for penetration but not completely hard) in 2 and 2/4 (penis is hard but not enough for penetration) in 1. There were no complications, and all subjects felt that Viberect would be a reasonable, practical ED treatment.

Conclusion: This study provides evidence that Viberect produces a non-invasive, well-tolerated erectogenic effect. These results indicate that penile vibratory stimulation provokes erections via neurostimulatory principles and support further study of this modality in treating men with ED.

Key Words: erection, bulbocavernosus, reflex, Rigiscan

Introduction

Current treatment strategies for erectile dysfunction (ED) target the vascular supply of the penis to promote increased penile blood flow and engorgement. The most commonly employed medical therapy for ED, namely phosphodiesterase type 5 inhibitors,¹ as well as other pharmacologic treatments, such as intracavernosal penile injection therapy and intraurethral alprostadil suppositories, adhere to this paradigm and have been proven to be highly successful in treating ED and improving patients' quality of life.² Another commonly used non-invasive means for ED treatment, the vacuum erection device, functions by externally applied negative pressure to the penile shaft that draws mixed arteriovenous blood into the penis, and a constriction ring is

applied at the base of the penis for blood retention.³ These strategies have also been studied in the context of penile rehabilitation after radical prostatectomy.⁴

The erectile mechanism is more complex, however, than solely relying upon hemodynamic changes to effect penile tumescence and rigidity. Integration of the vascular system with neurological, hormonal and psychological inputs by way of an intricate molecular network is necessary for physiologic erection.⁵ To date, while research efforts have focused on novel means of treating ED,⁶ investigation of non-vascular-based therapies is lacking.

Neuromodulatory strategies for the treatment of ED have been studied, mostly with respect to the administration of pharmacologic agents in the context of neurogenic ED associated with cavernous nerve injury following radical prostatectomy.^{7,8} Neuromodulatory nerve stimulation, defined as the application of electrical stimuli to nerves to alter neurotransmission processes in non-neurogenic and neurogenic conditions, has long been applied in the

Accepted for publication April 2013

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Figure 1. The Viberec handheld penile vibratory stimulatory device.

treatment of voiding dysfunction, in the form of sacral neuromodulation or selective peripheral nerve stimulation.⁹ Few studies specifically addressing how neurostimulation may impact erectile function exist.¹⁰

Vibratory devices have long been employed in sexual medicine for orgasmic dysfunction treatment. Penile vibratory stimulation (PVS) has largely been used for the treatment of anejaculation in the context of spinal cord injury.¹¹ Vibratory stimulation of genitalia is considered safe, devoid of significant side effects, and highly satisfactory in enhancing sexual responses in women.^{12,13} Little data exist in the literature, however, on the use of PVS for the treatment of ED. One report documents the use of penile vibration with a variable amplitude oscillation device to enhance the erectile response to intracavernosal injection of vasoactive drugs in the context of ED diagnosis.¹⁴

The aim of this proof-of-principle study was to assess the erectogenic stimulatory potential of the Viberec device (Reflexonic, LLC, Chambersburg, PA, USA) for the achievement of penile erection and rigidity. The Viberec is an FDA-cleared, CE- and Health Canada-certified handheld penile vibratory stimulatory device approved for the treatment of ED and ejaculatory dysfunction, see Figure 1.

Materials and methods

Participants

After institutional review board approval was obtained for the study, subjects were recruited by poster advertising (posted for 1 month prior to initiating the study) and consented to participate. Men aged 20-45 with normal erectile function as defined by the International Index of Erectile Function-Erectile Function (IIEF-EF) domain score¹⁵ were included

(IIEF-EF > 26/30). The men received a nominal compensation (\$50 US dollars) for their participation. A total of five participants were studied.

Study protocol

After providing informed consent, the subjects were brought into a private room and familiarized with the features and operation of the Viberec device. Initially, they were taught penile stretching exercises, wherein the glans penis is grasped between the thumb and forefinger on each side at the level of the coronal sulcus, and the penis is gently stretched to its elastic limit. Then, the penis is briskly stretched an additional 1-2 inches. By performing this motion, a reflexive erection response is generated. The subject was queried about his erection response with the Erection Hardness Score (EHS),¹⁶ for subjective assessment of maximal rigid erection responses.

Viberec treatment

The technique for operating the Viberec handheld device was then demonstrated: it is applied to the penis using the individual's dominant hand (alternatively, it can be applied by his partner), with vibratory pads positioned on the dorsal and ventral penile surfaces. Next, the Rigiscan system (TIMM Medical Technologies, Eden Prairie, MN, USA) for assessing erectile rigidity was applied to the penis. It was set to the provocative ambulatory mode and activated. The subject was left alone at this point in a darkened, quiet, private room, and 15 minutes was allowed to elapse to establish the baseline reading. After the initial 15 minutes had passed, he was instructed to turn on the Viberec device and apply it to his penis at the initial preset settings of 75 Hz, with only the ventral pad activated (this setting is most commonly employed initially). No visual sexual stimulation instruments were provided. He was instructed to apply PVS until he perceived that his most rigid erection was obtained, and then to maintain it for a total of 3 minutes with or without resuming PVS. After 3 minutes, the subject was given a full 20 minutes for full detumescence. At the conclusion of the session, he was again queried with the EHS to assess his own maximal rigid erection response. All subjective comments regarding the functionality and toleration of the device were recorded.

Treatment evaluations

Rigiscan data were analyzed using the Rigiscan Plus computer program. Data from both the penile tip and base were collected. Analysis parameters were: average penile rigidity (represented as a percentage of the maximal erection achieved), tumescence

percentage above baseline, the proportion of time in which rigidity exceeded 60% of full rigidity,¹⁷ and increase in penile girth (cm).

Results

Mean age of the study participants was 26.4 years (range 23-30). Four of the subjects had an IIEF-EF score of 30/30, the fifth 29/30. Although variable, there was definitely a subjectively measurable erectile response according to the EHS using the self-stimulatory BCR exercise alone.

Once the Rigiscan was applied and treatment commenced, there was a notable erectile response with the Viberec. Average basal rigidity was 41.3% of maximal recorded tumescence, and mean increase in basal rigidity above baseline was 29%. Penile girth increased by a mean of 2.5 cm in base circumference. The proportion of time wherein rigidity exceeded 60%, considered clinically meaningful and meeting the threshold needed for vaginal penetration, was 31.4%.

Subjective EHS scores following Viberec treatment was 4/4 in two subjects, indicating that "The erection is completely hard, rigid, and able to penetrate easily and sustained for a relatively long time", 3/4 in two subjects, indicating that "The erection is hard enough for penetration, but not completely, and it is not sustainable". For the fifth subject, his EHS score was 2/4, indicating that "The penis is hard, but not hard enough for penetration".

There were no complications, and the subjects all tolerated the Viberec device well. Of note, three of our five subjects noted some complaint with the Rigiscan in particular, and one felt that it (and specifically not the Viberec device) in particular detracted from his ability to achieve his best possible erection.

Discussion

The purpose of this clinical feasibility study was to verify the efficacy of PVS using the Viberec handheld device for provoking erectile responses. If this outcome is demonstrated, the use of PVS (specifically with the Viberec device) as a novel instrument to treat ED beyond the modalities that are currently available is worthy of further clinical investigation. We showed that, both subjectively with a validated questionnaire and objectively with Rigiscan measurements, the Viberec device effectively elicits an erectile response. This concept represents a new modality for the treatment of ED: a neurophysiologic mechanism for the stimulation of erection, not just an effect at the vascular response level. Thus, Viberec may add to current ED technologies, offering an alternative approach that more closely exploits and mimics normal biologic erections.

From a neurophysiologic viewpoint, penile erection is a culmination of multiple successful nerve reflexes which then initiate a vascular event. Erection is controlled by spinal autonomic centers, the activity of which is dependent on input from supraspinal centers and the genitalia. Sensory information, captured by receptors in the penile glans and shaft, is relayed via the dorsal nerve of the penis and perineal nerve to the afferent pudendal nerve, which is then relayed to the spinal cord. Efferent stimuli are subsequently transmitted to the penis via the cavernous nerves. Of additional anatomic importance, it is known that the pudendal nerves directly connect with the cavernous nerves at the base of the penis in 70% of cases.¹⁸ Genital afferent nerve vibratory stimulation can lead to reflexogenic gradual filling of the penis with arterial blood by activating the pudendo-cavernosal reflex.¹⁹ Additional physiologic effects include progressive rhythmic contraction of the perineal muscles via activation of the bulbocavernosus reflex (BCR), which contributes toward erection rigidity.^{20,21} Subsequent orgasm and ejaculation may be amplified due to stronger contraction of the bulbospongiosus muscle and activation of higher ejaculatory centers, summarized by Valles-Antuña et al.²²

The utilization of the BCR was meant to familiarize the subject with the concept of reflexive erection (akin to a run-in phase of a pharmaceutical trial in this research context).²³ In fact, it is recommended to perform this exercise prior to Viberec application.²⁴ Doing this exercise presumably relaxes the patient in advance of Viberec application. Indeed, the BCR, via pudendal nerve efferent stimulation, induces contraction of the bulbocavernosus and ischiocavernosus muscles,²⁰ which produces the rigid erection phase.²¹

An optimal regimen by which Viberec is used remains to be determined. A wide range of vibration frequency settings, from 70-110 Hz, are available. Additionally, stimulation may be set for the dorsal or ventral penile surface, or both. Although a "dose-response" assessment of different stimulation settings would have been an interesting study design feature, the recommended duration of use of the Viberec device is no more than 10 minutes daily at one session (as prolonged use is a possible safety concern associated with effects, such as penile numbness or skin irritation), and such a protocol at this time would have exceeded this limit.

By patient report in our study, the Viberec handheld device was not cumbersome to use, and the patients could see themselves using this as a treatment for ED. No adverse effects were noted with either performing the BCR exercise or using the Viberec device. While it would have been ideal to assess the practicality and erectogenic capacity of the Viberec device in a larger

sample of subjects, it was felt that the purpose of the study was achieved after studying five healthy volunteers.

Despite the proof-of-principle purpose of this study, several limitations are possible nevertheless. This was a small study consisting of five healthy participants with no documented ED. It is difficult to predict whether patients with ED would have similar responses, especially those with a neurological component to their ED, or a neuropathy, such as diabetes, who may sustain a substandard vibratory response. As well, although in our opinion the Rigiscan is an acceptable method to gauge erectile rigidity, this tool is not unequivocally accepted by the urological community.²⁵ Finally, although it would have been ideal to apply a direct objective measurement of reflexive erection neurophysiologically, currently available clinical tools, such as nerve conduction studies, genitocerebral evoked potentials and possibly biothesiometry, are impractical, invasive, and non-specific.²⁶⁻²⁸

This clinical feasibility study provides support to develop PVS, and in particular, the Vibrect handheld device, as a novel modality for the treatment of ED. The subjects studied herein reported satisfactory erections for penetrative intercourse using the Vibrect as the source of PVS, and comments about the practicality of the treatment were uniformly positive. Further evaluation of the safety and tolerability of the device, in standard clinical trial assessment fashion, is required. In addition, establishing efficacy of this therapy for treating ED and possibly serving a penile rehabilitation role in different ED populations, such as organic and post-radical prostatectomy ED patients, is warranted. □

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