

CASE REPORT

Safety and efficacy of a new device for inducing ejaculation in men with spinal cord injuries

SM Castle, LC Jenkins, E Ibrahim, TC Aballa, CM Lynne and NL Brackett

Study design: Prospective case series.**Objectives:** Male infertility is a common sequela of spinal cord injury (SCI). Fatherhood is a goal in this group of young patients; however, most are anejaculatory. Penile vibratory stimulation is recommended as the first line of treatment for this condition. Our study evaluated the safety and efficacy of a new device designed to induce ejaculation in these patients.**Setting:** The Miami Project to Cure Paralysis, Miami, FL, USA.**Methods:** The Viberec-X3 (Reflexonic, Frederick, MD, USA) was applied to 30 consecutive anejaculatory men with SCI whose level of injury was T10 and rostral.**Results:** The ejaculatory success was 77% (23/30). No adverse events occurred, and there were no malfunctions of the device.**Conclusion:** In this first report on the efficacy of the Viberec-X3 for treatment of anejaculation in men with SCI, we conclude that the device is safe and effective for inducing ejaculation in men with SCI. Recommendation of the Viberec-X3 versus other devices intended for this purpose should not be made until randomized controlled trials are performed.*Spinal Cord* (2014) **52**, S27–S29; doi:10.1038/sc.2014.110

INTRODUCTION

Every year, there are ~12 000 new cases of spinal cord injury (SCI) in the United States,¹ and thousands more worldwide. Most spinal cord injuries occur in young males.¹ Following SCI, the majority of men become anejaculatory and require medical assistance to procure sperm.² Only 10% of men with SCI can ejaculate via masturbation.³

Owing to its safety, cost and reliability, penile vibratory stimulation (PVS) is recommended as the first line of therapy for anejaculation in men with SCI.³ PVS typically is performed by applying a single vibrator to the dorsum or frenulum of the glans penis. During any PVS procedure, care must be taken to manage adverse symptoms such as autonomic dysreflexia and penile skin edema/abrasion.^{4,5} Historically, a wide variety of ejaculation success rates (19–96%) have been reported from PVS of men with SCI, with the highest success rates achieved by devices capable of delivering amplitudes ≥ 2.5 mm and 100 Hz, applied to men whose level of injury was T10 and rostral.^{3,6,7}

Failures (22%) may be salvaged by ‘sandwiching’ the penis between two vibrators;⁸ however, this maneuver can be cumbersome to perform. A new vibrator has been developed to achieve, in a single device, simultaneous stimulation of the dorsum and frenulum of the penis (Viberec-X3, Reflexonic, Frederick, MD, USA; Figure 1). To date, there are no reports on the efficacy of this device for inducing ejaculation in men with SCI. The purpose of our study was to evaluate the ejaculatory success rate and safety of the Viberec-X3 in anejaculatory patients with SCI.

MATERIALS AND METHODS

The study was approved by our Institutional Review Board. Subjects were men with SCI enrolled in the Male Fertility Research Program of the Miami Project to Cure Paralysis. All signed informed consent documents. We prospectively studied 30 consecutive SCI subjects who were unable to ejaculate by sexual intercourse or masturbation. Ejaculatory response to PVS relies on an intact spinal reflex arc;³ therefore, subjects with injuries caudal to T10 were excluded from the study. All patients received one trial of PVS with Viberec-X3. All patients were familiar with PVS and had been administered one or more previous trials with an alternate device. The present study was not designed to compare the success rates of various PVS devices, but simply to assess the ejaculation success rate with Viberec-X3.

Prior to PVS, subjects whose level of injury was T6 or rostral were administered 10–40 mg nifedipine sublingually to manage autonomic dysreflexia. Viberec-X3 was administered at the non-adjustable manufacturer settings of 4 mm amplitude and 70–100 Hz. Based on our previous studies, PVS was performed in 2–5 min intervals, interspersed by 1–2 min rest periods, for up to three intervals of stimulation, or until ejaculation occurred.³ Blood pressure was recorded at 1 min intervals throughout the procedure. Each patient was monitored for adverse symptoms, including penile bleeding or edema. The vibrator pads were thoroughly cleansed with 70% alcohol between each patient use.

RESULTS

Details of patient information are listed in Table 1. The result of the PVS procedures was that 23 of the 30 patients (76.7%) ejaculated. No adverse symptoms were noted. All patients tolerated the procedure well. The Viberec-X3 device did not malfunction during any of the stimulations.

DISCUSSION

PVS is thought to cause ejaculation via stimulation of the dorsal penile nerve.⁹ In order to achieve ejaculation, the penile vibrator must



Figure 1 Viberec-X3 (Reflexonic, Frederick, MD, USA) is a new device for inducing ejaculation in men with spinal cord injury. The device can stimulate, simultaneously, the dorsum and frenulum of the glans penis, via two vibrating surfaces, as seen here.

appropriately stimulate this nerve. Earlier reports showed low-amplitude vibrators to be inferior to high-amplitude vibrators for inducing ejaculation in men with SCI.¹⁰ Viberec-X3 deploys high-amplitude (4 mm) vibration via two sites in a single device. Viberec-X3 represents a new option for these patients. The success rate obtained in our study (76.7%) was slightly lower than previously published PVS success rates.³ This new penile vibrator appears to be safe and reliable in our cohort. For practitioners who have administered PVS with other devices, the learning curve is quite short, that is, one to two trials should be sufficient to successfully administer Viberec-X3. Prior to the patient self-administering this device at home, an experienced practitioner should supervise the patient's ability to safely and effectively administer the Viberec-X3.

Previous research has described maneuvers to salvage patients who fail to ejaculate with the administration of one single-headed vibrator. Such maneuvers include sandwiching the penis between two single-headed vibrators, administration of abdominal electrical stimulation in conjunction with PVS and administration of medications such as midodrine (for a review, see Brackett *et al.*³). The current study did not assess the ability of Viberec-X3 to salvage failures to a single-headed vibrator.

In this first report on the efficacy of Viberec-X3 for treatment of anejaculation in men with SCI, we conclude that the device is safe and effective for inducing ejaculation in men with SCI at or rostral to T10.

Table 1 Patient demographics and ejaculation trial outcomes

ID	LOI	COI	Age	YPI	Ejaculation with a previous vibrator?	Ejaculation with VibX3?	Time to ejaculation (s)	Lowest BP	Highest BP	Vol (ml)
1	C1	I	37	7.1	Yes	No	NA	105/61	120/77	NA
2	C4	C	36	14.9	Yes	Yes	14	97/68	155/94	1.7
3	C4	I	32	16.0	Yes	Yes	63	116/49	157/74	1.4
4	C5	C	21	1.1	Yes	Yes	50	107/48	137/70	2.3
5	C5	C	23	2.4	Yes	Yes	60	103/39	129/60	1.6
6	C5	C	27	10.6	Yes	Yes	43	94/45	129/61	2.5
7	C5	I	51	10.8	Yes	Yes	30	106/39	130/66	3.3
8	C5	I	47	29.7	No	No	NA	95/53	126/73	NA
9	C6	C	23	4.8	Yes	Yes	33	100/50	163/82	1.3
10	C6	C	29	4.9	Yes	Yes	30	108/44	129/66	1.8
11	C6	I	47	9.7	No	No	NA	103/56	151/74	NA
12	C6	C	42	21.2	Yes	Yes	34	73/36	143/84	1.8
13	C7	I	36	24.8	Yes	Yes	28	106/62	134/83	1.0
14	C8	C	30	10.8	Yes	Yes	120	100/43	112/50	3.5
15	T2	C	18	1.3	Yes	Yes	55	102/39	122/49	1.0
16	T2	C	50	2.8	No	No	NA	90/43	143/65	NA
17	T2	I	38	5.6	Yes	Yes	44	100/44	131/72	1.4
18	T3	C	22	3.4	Yes	Yes	65	85/30	94/37	1.1
19	T3	C	34	8.2	Yes	Yes	34	114/57	144/92	0.7
20	T3	C	27	10.9	Yes	Yes	40	113/42	122/47	2.0
21	T3	I	38	17.0	Yes	Yes	17	104/57	121/65	2.0
22	T4	C	22	3.7	Yes	Yes	50	93/39	118/50	2.5
23	T5	C	30	12.9	Yes	Yes	28	110/55	112/60	3.2
24	T6	C	26	3.4	Yes	Yes	28	104/60	119/65	3.0
25	T6	C	31	5.6	Yes	Yes	52	115/72	126/69	1.5
26	T6	C	39	17.6	Yes	Yes	15	123/57	148/70	1.4
27	T7	C	52	26.9	No	No	NA	104/61	115/74	NA
28	T9	C	27	6.5	Yes	Yes	52	138/75	151/79	4.7
29	T10	I	43	8.7	No	No	NA	114/56	127/70	NA
30	T10	C	43	11.4	Yes	No	NA	109/59	150/78	NA
Mean ± s.e.m.			34 ± 1.8	10 ± 1.4						2.0 ± 0.2

Abbreviations: BP, blood pressure; C#, cervical; C, complete; COI, completeness of injury; Ejac with Prev Vib?, Did the patient ejaculate when administered a previous PVS trial with an alternate device (not the Viberec-X3)?; Ejac with VibX3?, Did the patient ejaculate with the Viberec-X3?; I, incomplete; ID, subject ID; LOI, level of injury; NA, not applicable; T, thoracic; Time to Ejac, How many seconds it took for the patient to ejaculate with Viberec-X3; Vol, Antegrade semen volume in milliliters; YPI, years post injury.

Recommendation of Vibrect-X3 versus other devices intended for this purpose should not be made until randomized controlled trials are performed.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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