

ORIGINAL ARTICLE

Comparison of three methods of penile vibratory stimulation for semen retrieval in men with spinal cord injury

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Study design: Prospective, three-way crossover design.

Objective: Penile vibratory stimulation (PVS) is recommended as the first line of treatment for semen retrieval in anejaculatory men with spinal cord injury (SCI). This study compared ejaculatory success rates and patient preference for three methods of PVS within the same group of men with SCI.

Setting: Major medical university.

Methods: Fifteen men with SCI each received three methods of PVS. Method 1 (M1): applying one FertiCare Personal device to the dorsum or frenulum of the glans penis; Method 2 (M2): ‘sandwiching’ the glans penis between two FertiCare devices; Method 3 (M3): sandwiching the glans penis between the two vibrating surfaces of the Viberec-X3 device. The order of M1, M2 and M3 was varied to control for sequencing effects. Following each PVS trial, subjects rated their experience on a questionnaire with scaled responses.

Results: Ejaculation success rates were high for each method; however, ejaculation latency was significantly longer with M3 compared with M1 or M2. In survey questions about patient preference, there were no significant differences between M1 and M2. In contrast, M3 was rated lower than M1 and M2 in patient preference. Semen collection may be more difficult with the Viberec device.

Conclusions: On the basis of these findings, we recommend attempting PVS with one FertiCare device. If that fails, use two FertiCare devices. Although the Viberec-X3 was preferred less by patients, it had similar efficacy as the Fericare vibrator(s) and may be suitable for home use by some patients.

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INTRODUCTION

There are ~282 000 persons living with spinal cord injury (SCI) in the United States. In 2016, there were 17 000 new SCI cases in the United States, with most injuries occurring between the ages of 16 and 30 years, 80% of which were males.¹ Consequently, a large proportion of men with newly diagnosed SCI will be at what is considered their prime age of fertility. With no significant decline in long-term mortality in males with SCI, the focus in these men shifts to quality of life.²

After injury, many SCI patients naturally inquire about their attractiveness, relationships and ability to father children.³ Infertility is one of the most disheartening sequelae of SCI, a problem primarily caused by anejaculation and poor semen parameters (for example, low motility and low viability).^{4–6} Moreover, only about 9% are able to ejaculate via masturbation.⁷ The majority of males with SCI who wish to achieve pregnancy, therefore, require medical assistance to obtain sperm for assisted conception procedures.^{8–10}

Nonsurgical methods to obtain semen include penile vibratory stimulation (PVS), electroejaculation (EEJ) and prostatic massage. Although both PVS and EEJ are highly effective, PVS is recommended as the first-line therapy for anejaculation in men with SCI because of its safety profile, reliability and cost-effectiveness.^{11,12} PVS is performed by applying a single vibrator pad to the dorsum or

frenulum of the glans penis. During stimulation, care must be taken to prevent adverse reactions such as autonomic dysreflexia and penile skin abrasion. The highest ejaculatory success rates are attained by devices capable of delivering amplitudes of 2.5 mm and 100 Hz in men whose level of injury is T10 and rostral.¹³ Failures can be salvaged using the ‘sandwich’ method by using two vibrators to simultaneously stimulate the dorsum and frenulum of the penis.¹⁴ The Viberec-X3 device was introduced in 2013 for the purpose of inducing ejaculation in anejaculatory men with SCI. This device has two built-in vibrating pads that can simultaneously stimulate the dorsum and frenulum of the glans penis.¹⁵

With the availability of these three methods of performing PVS, what algorithm should be recommended? There are no reports directly comparing these methods within the same group of patients. The objective of the present study was to compare ejaculatory success rates, ejaculation latency and patient preference for three methods of PVS (one Fericare device, two Fericare devices and the Viberec-X3) within the same group of men with SCI.

MATERIALS AND METHODS

Subjects

The study was approved by the Institutional Review Board, and written consent was obtained from each subject. Subjects were participants in the

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Figure 1 Three methods of PVS were examined in this study. M1: application of one FertiCare device to the dorsum or frenulum of the glans penis. M2: 'sandwiching' the penis between two FertiCare devices. M3: Application of the Viberec-X3 device.

Male Fertility Research Program of the Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine in Miami, Florida. Eligibility criteria for the current study were men with traumatic SCI of more than 1 year duration, neurological level of injury at T10 or rostral, inability to ejaculate by sexual intercourse or masturbation and no contraindications for PVS. Fifteen subjects were enrolled. Their mean age was 37.3 ± 8.1 years, range 25–56 years. Their levels of injury are shown in Table 3.

Study design

In this prospective study, each subject received the following three methods of PVS, with an interval of 2–4 weeks between each method: Method 1 (M1)—applying one FertiCare Personal (Multicept, Denmark) device to the dorsum or frenulum of the glans penis; Method 2 (M2)—'sandwiching' the glans penis between two FertiCare devices; Method 3 (M3)—sandwiching the glans penis between the two vibrating surfaces of the Viberec-X3 (Reflexonic, Frederick, MD, USA) device. These methods are shown in Figure 1.

To control for sequencing effects, five subjects received PVS in the following sequence: M1, M2, M3; five subjects received the sequence M2, M3, M1; and five received the sequence M3, M2, M1. For trials with M1 and M2, FertiCare device(s) were set at 2.5 mm amplitude and 100 Hz. For trials with M3, stimulation parameters of the Viberec-X3 were preset by the manufacturer and were not adjustable.

PVS and Questionnaire

All subjects had their bladder emptied prior to performing PVS. For all methods, PVS was delivered in 2 min increments with inspection of the penile skin between increments. PVS was stopped if ejaculation occurred, or if no ejaculation occurred after 10 min of PVS. Blood pressure was monitored every minute throughout each procedure. Subjects whose level of injury was T6 or rostral were pretreated with 20 mg sublingual nifedipine to manage possible autonomic dysreflexia.^{16,17} Following each PVS trial, subjects were asked to rate their experience on a questionnaire with scaled responses. The measured distance from zero of a vertical mark on a 100 mm line indicated a rating between 0 and 100 (Figure 2).

The same operators performed all PVS methods, timing, administering and scoring of the questionnaire.

Statistical analysis

Repeated measures analysis of variance was used to compare differences between groups using GraphPad Prism 5.0 (GraphPad Software, Inc., La Jolla, CA, USA). Statistical significance was considered at $P \leq 0.05$.

RESULTS

All 15 subjects underwent the three methods of PVS. The ejaculation success rates for M1, M2 and M3 were 87, 100 and 87%, respectively (Table 1). The average ejaculation latency was significantly longer with M3 compared to M1 and M2 (56.8 s vs 29.6 and 32.2, respectively, Table 1).

Table 2 shows outcomes for post-stimulation survey Questions 1 through 4. For Question 1 (How much did this method meet your expectations?), PVS with the Viberec-X3 (M3) was rated significantly

lower than PVS with one or two FertiCare devices (M1 and M2, respectively). A similar outcome was found for Question 2 (How comfortable did you feel during stimulation?) and Question 4 (Would you recommend this method to other men with spinal cord injury?). For Question 3 (How comfortable do you feel about using this method at home either by yourself or with a partner?), M3 was also rated lowest, but the mean rating for this method (67.5) was not statistically significantly different from the mean ratings for M1 (79.1) or M2 (71.5).

Table 3 shows the results of Question 5 (If you ejaculated with this method, how pleasurable was the ejaculation?) and Question 6 (Did you experience any unpleasant sensations during PVS?). Subject's ratings on Question 5 varied between 0 and 100 for each method, with a mean \pm s.e.m. rating of 42.5 ± 10.9 , 45.1 ± 8.4 and 48.7 ± 9.5 for M1, M2 and M3, respectively (not statistically different). There was no distinct pattern in ratings of how pleasurable the ejaculation was by method of PVS. For example, four subjects gave the highest rating to M1, four subjects gave the highest rating to M2, four subjects gave the highest rating to M3, two subjects gave the highest rating to two methods, and one subject ejaculated with only one method.

Only four subjects per method reported experiencing unpleasant sensations during PVS (indicated on Table 3). The sensations most often reported were contractions (four subjects during each of methods M1, M2 and M3), tightness in chest (one subject during M2, two subjects during M3), 'unpleasant feeling in stomach' (one subject during M1 and M3, and headache (one subject during M3). In general, occurrence of unpleasant sensations did not seem to be related to the subjects' rating of how pleasurable the ejaculation was, with the possible exceptions of subjects no. 4 and no. 13. For example, subject no. 4 gave ratings of 54 and 48 to M1 and M2, respectively, during which he reported no unpleasant sensations, versus a rating of zero for M3, during which he experienced unpleasant contractions and tightness in the chest. In contrast, subject no. 13 gave a rating of zero for M1 and M2, during which he experienced unpleasant contractions, versus a rating of 53 for M3 during which he experienced no unpleasant sensations.

It should be noted that the unpleasant sensations did not preclude subjects from participating in the study. No subject requested that a procedure be aborted. No subject declined to continue in the study.

DISCUSSION

PVS is considered the method of first choice for semen retrieval in men who are anejaculatory due to spinal cord injury.¹¹ Compared to the alternative semen retrieval method of EEJ,¹⁸ PVS results in better semen quality,¹⁹ is preferred more by patients²⁰ and can be performed by selected couples wishing to attempt home insemination.⁸ Consequently, clinicians have sought to optimize the efficiency and success rate of PVS. For example, previous research found that

Instructions: place a vertical mark on the line to indicate your response.

1) How much did this method meet your expectations?

Did not meet expectations **Met expectations**

2) How comfortable did you feel during stimulation?

Not relaxed **Very relaxed**

3) How comfortable do you feel about using this method at home either by yourself or with a partner?

Not comfortable **Very comfortable**

4) Would you recommend this method to other men with spinal cord injury?

Would not recommend **Would recommend**

5) If you ejaculated, how pleasurable was this ejaculation?

Not pleasurable **Very pleasurable**

6) Did you experience any unpleasant sensations during the procedure? **YES** **NO**
If **YES**, please describe what you felt:

7) Other comments:

Figure 2 PVS Questionnaire.

Table 1 Ejaculatory success rate and ejaculatory latency in three different methods of PVS

	M1	M2	M3
Ejaculatory success rate (% of men ejaculating)	87	100	87
Ejaculation latency (mean ± s.e.m. in seconds)	29.6 ± 5.0	32.2 ± 4.4	56.8 ± 5.0 ^a

M1 = method 1: application of one FertiCare device.
M2 = method 2: 'sandwiching' the penis between two FertiCare devices.
M3 = method 3: application of the Viberec-X3.
^aSignificantly different from M1 ($P \leq 0.05$) and M2 ($P \leq 0.05$).

application of two FertiCare devices salvaged 22% of failures to one FertiCare device.^{14,21,22} The introduction of the Viberec-X3 in 2013 provided another tool for inducing ejaculation in this population.¹⁵ The purpose of the present study was to compare the efficacy and success rate of the three methods of PVS applied to the same patient.

Only men with a neurological level of injury at or rostral to T10 were selected for this study because injuries caudal to T10 may interfere with the ejaculatory reflex arc necessary for the success of PVS.²³

The application of 2 FertiCare devices (sandwich method, M2) resulted in the best success rate (100%) compared to the other two methods (87% for both M1 and M3). The Viberec-X3 method (M3) required more time to induce ejaculation than the single FertiCare method (M1) or the sandwich method (M2). Following each PVS trial, patients were asked to answer a survey about their experience. The Viberec-X3 (M3) was the least preferred method, and the single FertiCare method (M1) was the most recommended method by the study subjects. Subjects' reasons for preferring one method over another were variable. For example, the reasons given by subjects who preferred M1 (application of one FertiCare) included the following: 'it is effective and you get good results,' 'good feeling,' and 'it is fast and easy.' Reasons given by subjects who gave a lower rating for M3 (Viberec-X3) included the following: 'it did not feel right,' 'not as fast

Table 2 Survey responses following each of three different methods of PVS

	M1	M2	M3
Question 1:			
How much did this method meet your expectations?	74.9±6.1	77.2±6.1	52.8±5.9 ^a
0 = did not meet expectations 100 = met expectations			
Question 2:			
How comfortable did you feel during stimulation?	82.2±5.7	82.2±5.7	64.3±5.5 ^b
0 = not comfortable 100 = very comfortable			
Question 3:			
How comfortable do you feel about using this method at home either by yourself or with a partner?	79.1±6.5	71.5±6.5	67.5±6.2
0 = not comfortable 100 = very comfortable			
Question 4:			
Would you recommend this method to other men with spinal cord injury?	91.7±7.0	83.6±7.0	68.4±6.7 ^c
0 = would not recommend 100 = would recommend			

Values shown are mean±s.e.m.
M1 = method 1: application of one FertiCare device.
M2 = method 2: 'sandwiching' the penis between two FertiCare devices.
M3 = method 3: application of the Viberec-X3.
^aSignificantly different from M1 ($P \leq 0.01$) and M2 ($P \leq 0.03$).
^bSignificantly different from M1 ($P \leq 0.03$) and M2 ($P \leq 0.03$).
^cSignificantly different from M1 ($P \leq 0.02$).

and easy to use' and 'when my penis is squeezed with the vibrator, it is more difficult to ejaculate.' Although M3 had the lowest mean rating for patient preference, there were individual subjects who preferred M3 to M1 or M2. For example, subject no. 13 commented that M3 was 'very comfortable, very fast and convenient.'

Although no clear definition for autonomic dysreflexia (AD) exists, it is described as a conglomeration of symptoms including headache, skin flushing, stuffy nose, diaphoresis, generalized feelings of unwellness and uncontrolled hypertension.²⁴⁻²⁷ It is generally accepted that a sudden dangerous rise in blood pressure is the major symptom of autonomic dysreflexia to be avoided. To this end, all subjects at risk for AD received 20 mg of nifedipine sublingually 10-15 min before beginning their procedure. All patients undergoing PVS during the study were monitored by a physician for signs of AD, and protocols were in place to stop the procedure if these symptoms were experienced. Most subjects experienced a rise in blood pressure with all three methods of PVS without other symptoms concerning for AD. No patients were bradycardic and heart rate did not change significantly from baseline during PVS. Those with elevated blood pressures became normotensive shortly after stimulation was stopped. However, three subjects complained of symptoms that tend to be associated with AD; subjects 4 and 15 complained of chest tightness after M3, and subject 11 complained of unpleasant abdominal sensation after M1 and M3. These symptoms were transient and briefly resolved after ejaculation without clinically significant sequelae. Chest tightness was only experienced with M3. Whether this was associated with longer latency to ejaculation remains to be clarified

Table 3 Sensations during ejaculation

Subject ID no.	Level of injury	Method of PVS		
		M1	M2	M3
1	T10	0	0 (C)	N.E.
2	T6	36	26	51
3	C5	52	47	30
4	C1	54	48	0 (C, T)
5	T3	93	100	100
6	T4	0 (C)	49 (C)	62 (C)
7	T4	6	29	0
8	C5	N.E.	38	58
9	C5	70	86	59
10	C5	N.E.	42	N.E.
11	T4	99 (C, S)	100	90 (C, S)
12	C2	1	0	0
13	T4	0 (C)	0 (C)	53
14	C8	100	64	92
15	C8	42 (C)	47 (C)	39 (C, T, H)
Mean ± s.e.m.		42.5 ± 10.9	45.1 ± 8.4	48.7 ± 9.5

Not significantly different

Abbreviations: C, contractions; H, Headache; N.E, no ejaculation; S, Unpleasant feeling in stomach; T, Chest tightness.
After each ejaculation, subjects were asked to indicate 'how pleasurable was this ejaculation?' (Survey Question 5). Subjects' ratings are shown from 0 = Not Pleasurable, to 100 = Very Pleasurable. Subjects were also asked whether they experienced any unpleasant sensations during ejaculation (Survey Question 6). Outcomes are shown in parentheses.
Level of injury: C = cervical, T = thoracic.
M1 = method 1: application of one FertiCare device.
M2 = method 2: 'sandwiching' the penis between two FertiCare devices.
M3 = method 3: application of the Viberec-X3.

owing to our small sample size. No specific method had a strong correlation to AD. Notwithstanding, the risk for AD during PVS can be minimized through a protocol that includes pre-treatment with oral nifedipine, frequent blood pressure monitoring and close observation. In our experience, performing PVS with any of the three methods, is by and large, safe.

At the time of the performance of this study, the cost of the FertiCare device is ~\$800 per unit versus the Viberec-X3, which is ~\$300 per unit. The Viberec-X3 thus represents a lower cost option, which may be appropriate for some patients. From the standpoint of clinicians attempting to collect semen for insemination, we found semen collection to be more problematic with M3 versus M1 or M2 because of the configuration of the Viberec-X3 device, which hampered proximity of the specimen cup to the urethral meatus.

CONCLUSIONS

Our recommended algorithm is to attempt PVS with one FertiCare device. If that fails, use two FertiCare devices. Although the Viberec-X3 was preferred less by patients, it is a lower cost alternative that may be suitable for home use by some patients.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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