A Survey of SCI Individuals Who Use a Ferti CareR Personal Vibrator: Reproduction, Bladder Program, Spasticity and Quality of Life

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Citation

Abstract

Introduction: For individuals with spinal cord injury, the Ferti CareR personal vibrator can be applied to the genitalia for reproductive health and orgasm. In addition, reports of vibratory effects on spasticity and bladder inhibition have been reported. However, there is no reported owner survey for the device’s home-use, either benefits or problems. Methods: 122 SCI individuals (69% response rate) who had been using the device for 2 to more than 4 years completed a mailed survey which included a wide range of device related questions. Results: Respondents were primarily males (90%) between 20 and 60 years old. Seventy-two percent had cervical or upper thoracic injury and 56% had complete injuries; 91% are using the device currently, but 48% have periods of nonuse. They were using it for orgasm (ejaculation, 84%) and sexual activity (68%). Most respondents also perceived improvement since starting to use the device in health areas including: overall health (70%), quality of life (96%), leg spasticity (80%), sleeping (65%), decreased urinary incontinence episodes (71%) and decreased rate of urinary tract infections (57%). Help with having 22 children was reported by 14 owners. Problems with use included few or no erections (77%), skin problems (13%), and needing medication for high blood pressure during use (10%). Conclusions: This is the first survey of use and nonuse of vibratory therapy by individuals with SCI. High percentages of respondents reported benefit in areas of sexual health, quality of life, spasticity relief and bladder inhibition. Problems with use were limited. Thus, vibratory therapy should be considered further in SCI rehabilitation programs as well as for continued outcomes research.

INTRODUCTION

Assistive technology continues to improve the lives of those with spinal cord injury (SCI)[1-3] The Ferti CareR personal vibrator is a hand-held, home-use device that is applied to the genitalia to produce orgasm. The device is usually prescribed as an assistive device for reproductive health [1-5] A few studies limited by the small number of patients studied have also shown benefits with regular vibratory therapy to reduce spasticity, urinary incontinence, as well as suggested improvement in quality of life [6,9-11] However, there is no study of owner perceptions of benefits or problems with home-use. Thus, a national survey was conducted in the United States including use and nonuse of vibratory therapy.

MATERIALS AND METHODS

The Ferti CareR personal vibrator is a hand-held device that produces vibrations on a 3.5 cm diameter round plate (photos of the device are published and available at the distributor’s web site [7,12]. It is manufactured by Multicept Inc, Denmark and distributed by a web based company in the United States [12]. Product information for vibrator use by those with spinal injuries includes advice on using 2.5 mm stroke length and at 100 Hz to produce an orgasm [4,12]. For males, vibration is applied against the lower side of the frenulum of the penis with the thumb placed over the head of the penis to hold it down against the vibrating plate. For females, it is applied against the clitoris. There is an indicator light to show if too much force is being applied. Vibrations are continued until orgasm occurs or for a maximum of 3 min. If no orgasm occurs, repeated use after 1 min can be conducted if there is no genital skin irritation or autonomic dysreflexia. Product information states that the frequency of use should not be more than once every 24 hours. Warnings include risk for superficial trauma to the skin resulting in bruising, bleeding or superficial ulceration.
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and to not use it over edematous or inflamed areas of skin, and that it should not be used when the patient has unexplained calf pain because of the risk of deep venous thrombosis. Furthermore, vibrations in SCI individuals with lesions above T6 have a risk of autonomic dysreflexia. Medication can be given to manage the autonomic dysreflexia [6-8]. It is recommended that at least two vibration procedures be performed in the clinic to set safe conditions for home-use.

A 37 question survey was developed by the authors. Standard Likert type items as questions and answers were developed that emphasized effects since starting to use the device. Questions included demographic, vibration parameters, perceived effects in medical areas and side effects. The following are examples of standard questions:

Figure 1

The questionnaire was sent by staff at the web-based US distributor of the device [12] with a cover letter that did not include corporate advertising and asked for return of the filled out questionnaire in an enclosed and stamped envelope to the company. The mailing in May of 2009 was to 200 sampled customers with SCI who had purchased a Ferti CareR Personal vibrator between September 2004 and December 2007. Sampling methods by the company consisted of the first 5 SCI purchasers each month during this 40 months period. The company received the returned questionnaires between June and August of 2009. Thus, the period of device experience was between 1 year, 6 months and 4 years, 3 months. There were 23 returned questionnaires due to wrong address; thus, 177 actually received the questionnaire and 122 returned filled-out questionnaires for a 69% response rate. Some of those surveyed may have purchased a second vibrator. The life expectancy of the device is 6 years and as many as 25% of original buyers are buying a second device (personal

Communication, David Buck, President of US distributor of the vibrator0[12]. For the returned questionnaires, one company employee entered all of the data into a spread sheet and all entries were checked for accuracy by a second employee to avoid any bias in data entry. The database was sent electronically to the authors for reporting the results of the survey.

No IRB review board was used for this survey (due to the high costs of an independent IRB for Corporate research); however, the survey was conducted in accordance with standard IRB required procedures and requirements of the Health Insurance and Portability Accountability Act (HIPPA) for this type of study. Thus, this corporate sponsored survey did not include identifiable data such as names, social security numbers or addresses, and returned questionnaires were kept confidential; they are kept in a locked cabinet at the Company [12]. No subject follow-up for returned questionnaires was conducted. The authors have no conflict of interests, no payments and there was no influence from the company regarding this publication [12].

RESULTS

The majority of respondents were male (90%) between 20 and 60 years old. Seventy-two percent had cervical or upper thoracic injury (Table 1, see Methods Area 1 questions). More than half reported injuries for less than 20 years (75%), complete injuries (56%) and a few walked (11%). The most injuries were caused by motor vehicle accidents (25%) and ‘Other’ (including gun-shot wounds) (51%).
The vibrator was currently being used by 91% of respondents; 36% had been using it for 1 to 2 years and 56% had been using it from 2 to more than 4 years (Table 2). Forty-percent of the respondents reported using it for more than 4 years and this may have been due to individuals that had bought a second vibrator (see survey methods for an explanation of the long reported use). The vibrator was most often being used from once every 2 days to once each week (83%). However, 48% reported sometimes stopping use for a month or more at a time. During use, the usual stroke length was 2.5 mm (80%), frequency was 100 Hz (92%), and one or two orgasms was usually produced with each use (81%). Only ‘sometimes or never’ was marked by 77% of respondents for the occurrence of erections with use.

A single question (Table 3 & see Methods Area 3 questions), asked about what the device was being used for with the following percentages of respondents: orgasm (84%), sexual activity (68%), spasticity relief (64%) and decreased overactivity of their urinary bladder (43%). Also included in Table 3 are data about problems with use. Problems included: needing medication for high blood pressure during use (10% of respondents), skin problems (13%) and personal problems (unspecific, 7%).
Eight questions asked about the impact of device use in medical problem areas commonly experienced by those with SCI. Possible answers to mark were ‘better, same, worse, other or not sure’ (Table 4, see Methods Area 4 questions). The percentage of respondents marking ‘Better’ for the eight areas were: sex life (97%), quality of life (96%), overall health (70%), leg spasms (80%), transfers (75%), sleeping (65%), high blood pressure (39%), and bowel program (20%; questions in the bladder area are reported below). In addition, few respondents marked ‘worse’ in these areas.

There was also a high percentage of respondents reporting benefits with use for their bladder program (Table 5 see Methods Area 5 questions). For bladder inhibition, ‘decreases’ were marked for: the number of urinary incontinence episodes (71%), use of urinary incontinence pads (34%) and use of bladder inhibitory medication (13%); they also reported drinking more water to increase their bladder volume (68%; Table 5A). In the bladder program area, ‘decreases’ were marked for: number of urinary tract infections (57%), bladder problems (48%), and urinary stones (1%) (Table 5B).
The final question was open-ended and asked the subjects to write any additional information, either benefits or problems, related to use or non-use of the device (see Methods Area 6 questions). There were 96 (#) comments from 62 respondents. There were only 3 negative comments and all were about the devices high cost. In contrast, there were 93 positive comments, but 17 of these could not be classified. Improved ejaculation and sex life was reported by 17. There were statements about improved quality of life (#5) and that they liked the product (#14). Positive statements also included holding more urine (#11) and less urinary incontinence (#4). The most comments were about reproduction: help with having 22 children was reported by 14 owners; current pregnancies by 6 and help with family planning by 6 owners.

**DISCUSSION**

The primary indications for a prescription for a vibrator device following SCI is for reproductive assistance. Ninety-eight percent of respondents reported orgasms (ejaculations) with use and many respondents reported assistance with having children, current pregnancies or family planning. These results are similar to previous findings where orgasms and ejaculation were reported for a majority of individuals with upper-motor-neuron SCI [4-8]. In addition, home-use of this device for reproduction is well known, and it is cost effective compared to clinical reproductive programs.

The vibrator was being used as described in product information: 100 Hz and 2.5 mm stroke length [4,12]. However, many were only using it once a week or less, and nearly half reported sometimes stopping use for a month or more at a time. A limitation of this study was that reasons for nonuse were not further queried. In addition, the product information does not state that there could be benefits of more frequent use of the device. In the area of safety, few respondents reported problems with use. Medical management of autonomic dysreflexia during vibratory therapy was detailed in the product information sheet and includes a recommendation for initial testing in the clinic (see Methods) [12]. Thus, safety concerns for this device appear to be manageable with medical oversight.

A surprising finding of this survey was the high percentage of owners reporting a wide range of benefits from the device for quality of life, leg spasms, transfers, sleeping, overall health, and sex life. For leg spasticity, initial vibration can induce leg, abdominal and pelvic floor muscle spasms. Ejaculation is usually associated with clonic muscle contractions [4-8]. Following orgasm, spasticity has been shown to be reduced for up to 3 hours [4,9]. In the quality of life area, prior studies have suggested improvements with vibratory therapy and a high percentage of respondents to this survey agreed with that benefit [6-8]. Thus, vibratory therapy warrants consideration in rehabilitation programs and for further study, especially in the area of quality of life.

Bladder program was another area where there were high percentages of respondents reporting perceived benefit. These included decreased UTI and incontinence. Vibratory inhibition of the SCI bladder has been reported in case and controlled studies [10,11]. The orgasm is thought to inhibit spinal reflexes. Also, the inhibitory effects may be longer.
lasting than those reported for neuromodulation [13,14]. Thus, vibratory therapy should be considered when bladder inhibition therapy is being sought for individuals with SCI.

There were limitations in this study. Patient-perceived benefit is dependent on their recollections, which may not be accurate. In addition, reported benefits in some areas like sleep and bowel programs may have been secondary to decreased leg spasticity. However, the high response rate to this mailed survey suggests limited biasing based on who filled out the questionnaire. Reliability was also probably improved by using single Likert item (questions & answers) for each area of interest and structuring answers to determine only whether or not change had occurred, not the amount of change [1]. Generalizeability may have been improved by the diverse demographic group surveyed including a wide range of ages, years of injury, cause of injury and years of device use. Secondary analysis such as the association between the amount of vibrator use and health benefits is not presented. The high percentage of patients reporting positive responses or 'not sure, does not apply,' limited the usefulness of secondary analysis. Ethical practices to avoid bias were used in this study; however, no IRB board was consulted (see Methods).

There are also questions about the optimal vibratory methods to produce outcomes. Is the movement of the Ferti Care® Personal vibrator optimal as it is limited to only up-and-down movement [4]? Other genital vibrators have up-and-down as well as sideways or rotating movements. With few patients in this survey reporting erection with use, different vibratory movements may be helpful in this area. Another important questions is: Are health benefits from vibratory therapy dependent on orgasm? For example, vibration on the dorsal side of the head of the penis can cause immediate spasms and abdominal muscle contractions, but seldom results in orgasm. Would this vibratory method also have health benefits?

This is our second study of owner’s perceptions of home-use, assistive-technology. The first study was a national survey of use of standing wheelchairs and standing devices [2,3] and was followed by a database study in an SCI clinic. [15-17]. Users of regular standing reported a wide range of benefits including improved quality of life and spasticity relief. In comparison, the current survey showed higher positive response rates in more health areas. Given the high rates of secondary medical problems in the population of SCI, rehabilitation programs should consider further the potential inclusion of these types of assistive technology. Standing and vibratory devices also need to be studied further in prospective randomized trials.

CONCLUSION
This is the first survey of SCI-owner’s perceptions of a home-use vibrator designed to promote orgasm and reproduction. A high percentage of respondents reported positive outcomes in these areas in addition to benefits in areas such as inhibition of spasticity and their overactive bladder, and improved quality of life. Few side effects of the therapy were reported. Vibratory therapy should be considered for inclusion in rehabilitation programs, and continued outcomes research of this therapy is warranted.

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A Survey of SCI Individuals Who Use a Ferti CareR Personal Vibrator: Reproduction, Bladder Program, Spasticity and Quality of Life

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