ORIGINAL ARTICLE

Effects of sacral neuromodulation on female sexual function

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Abstract The aim of this prospective study was to determine if sacral neuromodulation has an effect on the patient's subsequent sexual function. Sexually active patients that underwent an Interstim® Sacroneuromodulator implantation (Medtronic, Minneapolis, MN) for control of bladder symptoms were enrolled. A Female Sexual Function Index (FSFI) was completed before surgery and at a mean of 5.7 months postoperatively. Eleven subjects proceeded to permanent implantation, seven of these were sexually active before and after placement. Three subjects (43%) felt the device impacted on their sexual function in a positive way (1) by decreasing urgency and (2) by increasing desire. Overall sexual frequency increased significantly after the surgery (p=0.047). There were also significant increases in the FSFI total (p=0.002), and domain scores for desire (p=0.004), lubrication (p=0.005), orgasm (p=0.043), satisfaction (p=0.007), and pain (p=0.015). There was no correlation between patient report of urinary symptom improvement and FSFI scores. In

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W. A. Silva Pacific Northwest Urogynecology, PLLC, 34503 9th Ave S. Suite 330, Federal Way, WA 98003, USA conclusion, sacral neuromodulation may improve sexual frequency and sexual function scores in subjects with urgency frequency and urge incontinence.

Keywords Sacral nerve stimulation · Sacral neuromodulation · Sexual function · Sexual frequency

Introduction

Sacral nerve stimulation (Interstim[®], Medtronic, Minneapolis, MN) is a relatively new therapy for treatment of urgency frequency, urge incontinence, and nonobstructive urinary retention. The mechanism of action is largely unknown; however, it is felt to occur via modulation of the nerves to the bladder [1]. The lead is generally implanted at the S3 foramen, while the pulse generator is placed permanently in a subcutaneous pocket over the buttocks.

The nerves that arise from S3 include the pelvic, pudendal, and posterior femoral cutaneous nerves. Dermatomal distribution from this site involves the genitalia and lower and lateral buttocks. The pudendal nerve provides motor innervation to the muscles of the perineum, while the pelvic nerve travels to the inferior hypogastric plexus and plays a role in the function of the bowel and bladder. Sacral neuromodulation is FDA-approved for treatment of urinary urgency frequency, urge incontinence, and nonobstructive urinary retention. Promising results were also obtained for treatment of interstitial cystitis, pelvic pain, and fecal incontinence [2].

Despite the positive impact that sacral nerve stimulation has on function of the pelvic organs, little is known about its impact on female sexual function. While some studies have suggested a potential role for sacral neuromodulation



in the treatment of erectile dysfunction [2], it remains to be seen whether women will find it beneficial. However, anecdotal tales of enhanced arousal and orgasm with the device exist, suggesting positive impacts on sexuality. A recent study showed improvements in nine subjects' quality of sexual activity after implantation for fecal incontinence [3]. However, this was limited by a retrospective design, use of a nonvalidated questionnaire, and the fact that perceived improvement may have been related to reduction in fecal incontinence episodes. There are no published studies that report sexual function changes in women undergoing neuromodulation for urinary symptoms. The purpose of this pilot study was to prospectively assess sexual frequency and sexual function in women undergoing Interstim® implantation for control of bladder symptoms.

Materials and methods

This is a prospective two-center study of women undergoing Interstim® sacral neuromodulation for control of bladder symptoms between December 2003 and July 2005. Patients were selected to undergo this procedure if they had a diagnosis of urgency frequency, urge incontinence, or nonobstructive urinary retention and had failed conservative management including medications, physical therapy, and behavioral modification. The study took place at two sites: a private Urogynecology practice in Cincinnati, OH (site 1), and a private Urology practice in Springfield, IL (site 2). Interstim implantation was performed at S3 in a

two-stage procedure, with only those subjects reporting a greater than 50% improvement proceeding to stage II. The surgeons performing the procedure were experienced implanters (SM, SK, MK), performing approximately one to four procedures per month.

All patients undergoing Interstim implantation over this period were screened for eligibility in the study. Eligible subjects were those that considered themselves to be sexually active before implantation, in a stable heterosexual relationship. For this study, sexual activity was defined as sexual fantasies or thoughts, caressing or close physical contact, and self-stimulation or sexual intercourse. Eligible subjects signed written informed consent, and a Female Sexual Function Index (FSFI) was completed before their surgery. Postoperative surveys were mailed to subjects starting at 3 months postoperatively, and data were collected and analyzed by investigators at site 1. If surveys were not returned, patients were contacted by telephone and sent repeat mailings every 2 months. One subject was lost to follow-up until her 12-month postoperative visit; she completed the questionnaires that day. Postoperative information obtained included the FSFI, as well as questions regarding subjects' impression of bladder symptom improvement and whether they felt there was any impact on their sexual function (Table 1). Patients were asked to elaborate if they had any observations. The two sites gave Institutional Review Board approval for the study.

The Female Sexual Function Index (FSFI) is a brief instrument for assessment of sexual function that consists of 19 questions. The questions are grouped and scored for

| How much have your symptoms improved since implantation? | | | |
|--|---|--|--|
| | <10% | | |
| | 11-25% | | |
| | 26-50% | | |
| | 51-75% | | |
| | 76-90% | | |
| | >90% | | |
| Do you thinl | k the device impacted on your sexual experiences? | | |
| | NO | | |
| | YES | | |
| If you answered YES, can you describe this impact? | | | |

Please turn to the next page for the Female Sexual Function Index (FSFI)



domains of libido, arousal, lubrication, orgasm, satisfaction, and pain. The FSFI has been validated based on DSM IV diagnoses of desire disorder, arousal disorder, and orgasmic dysfunction [4, 5] and is intended for patients that have been sexually active in the prior 4 weeks. For this research, two questions were added to the FSFI. Question 1 asked about frequency of sexual activity and possible barriers if patients were not sexually active. Question 21 asked if completing the survey made them embarrassed or uncomfortable. To obtain a complete FSFI score, subjects must answer questions regarding symptoms with vaginal intercourse or sexual contact (maximum score 36). In subjects without any sexual contact, scores were analyzed based on the appropriate domains only.

Statistical analysis was performed with SPSS 13.0 for Windows (SPSS, Chicago, IL). Descriptive analysis including means and frequencies are reported in Table 2. Comparison between pre- and postoperative FSFI scores was performed using Paired Samples *t* tests after a normal distribution with a skewness statistic less than 3 was confirmed. A Spearman's rho correlation analysis was computed between FSFI scores and urinary symptom improvement.

Results

Thirteen patients were enrolled in the study. Two subjects did not proceed to permanent implantation and were therefore excluded. The mean age of subjects was 50 with a range of 28–75. Six women (55%) were postmenopausal

Table 2 Demographic information (*N*=11)

| Characteristics | Number (percentage) |
|--|---------------------|
| Age (mean) | 50±13.9 |
| Ethnicity | |
| Caucasian | 8 (73) |
| African American | 3 (27) |
| Marital status | |
| Married | 8 (73) |
| Unmarried (single, divorced, widowed) | 3 (27) |
| BMI (mean) | 29.5±7.8 |
| Premenopausal | 5 (45) |
| Postmenopausal | 6 (55) |
| Hormone replacement | 4 (66) |
| Smoker | 6 (55) |
| Parity (mean) | 2.1±1 |
| Previous surgery | |
| Hysterectomy | 8 (73) |
| Bladder repair/anti-incontinence procedure | 6 (55) |
| Depression | 3 (27) |
| Indication for procedure | |
| Urgency frequency | 5 (45) |
| Urge incontinence | 6 (55) |

with four on hormone replacement. Indications for the procedure were urge incontinence, and urgency frequency (Table 2). None of the subjects had fecal incontinence or chronic pelvic pain.

Four of the 11 subjects (36%) were unable to complete all sections of the FSFI either before or after placement. One subject had no sexual contact before placement due to incontinence, and this was resolved after surgery. One subject had no sexual contact after placement due to new-onset partner problems. Two subjects had no sexual contact both before and after placement, one due to low desire and the other due to pain. For these four subjects, only scores in the domain of desire were analyzed.

Postoperative surveys were completed at a mean of 5.7 months (3–12). Three of the seven subjects (43%) felt the device impacted on their sexual function in a positive way (1) by decreasing urgency and (2) by increasing desire. Number of sexual experiences in the past 4 weeks increased significantly after the surgery in the seven subjects who completed the FSFI (p=0.047).

FSFI domain and overall scores improved after the procedure (Fig. 1). There was a significant increase in the total score from 20.74 to 30.22 (p=0.002). Significant improvements were also noted in scores for desire (p=0.004), lubrication (p=0.005), orgasm (p=0.043), satisfaction (p=0.007), and pain (p=0.015). The only domain not to be affected was arousal, in which the mean scores pre- and postoperatively were the same.

Most subjects (64%) felt the device improved their urinary symptoms by at least 50% at time of the follow-up. A Spearman's rho correlation was performed between urinary symptom improvement and FSFI scores. There were no significant correlations between overall and FSFI domain

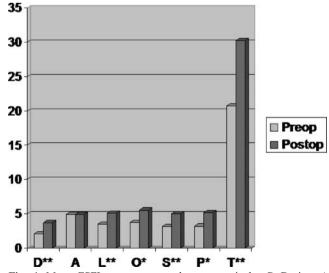


Fig. 1 Mean FSFI scores pre- and postoperatively. D Desire, A arousal, L lubrication, O orgasm, S satisfaction, P pain, T total. An asterisk indicates significance at the 0.05 level. Two asterisks indicate significance at the 0.01 level



Table 3 Correlation of urinary symptom improvement and FSFI scores

| | Correlation (r) | P value |
|-----------------------------|-----------------|---------|
| Desire (<i>N</i> =11) | 0.510 | 0.109 |
| Arousal (N=7) | 0.433 | 0.284 |
| Lubrication (N=7) | 0.050 | 0.906 |
| Orgasm (N=7) | 0.401 | 0.324 |
| Satisfaction (<i>N</i> =7) | 0.205 | 0.626 |
| Pain (<i>N</i> =7) | -0.605 | 0.112 |
| Total score (N=7) | -0.012 | 0.977 |

scores and perceived symptom improvement at follow-up (Table 3).

Discussion

This pilot study is the first to prospectively assess sexual function in subjects undergoing sacral neuromodulation for lower urinary tract dysfunction. Although the device is designed to nonselectively stimulate the nerves at S3 and thus may have resultant effect on all sites innervated by this root, it is not known whether this leads to any impact on sexual function. We demonstrated significant improvements in sexual frequency and sexual function scores in our subjects after Interstim® implantation.

The pudendal nerve arises from the anterior branches of S2–S4 and is largely responsible for sensory innervation of the perineum and clitoris [6, 7]. Indeed, anecdotal reports exist of multiple orgasms occurring in women with nerve stimulators implanted at S2 or above. Despite these implantations not helping incontinence symptoms, some of these women allegedly requested to keep their device. These accounts have led to an interest in the development of a nerve stimulator to treat female sexual dysfunction. We have also encountered subjects that described enhanced sexual sensations from standard Interstim® implantation. Thus, it is possible that sacral neuromodulation may lead to positive effects on the sexual response and sensation via stimulation of the pudendal nerve.

An interesting finding of these results is that only three subjects (43%) felt that the device impacted on their sexual function postoperatively; however, all subjects had an improvement in their total FSFI scores. This highlights the benefit of using a validated questionnaire as a more sensitive way to assess sexual function and the use of a prospective design to reduce bias. We were also surprised that mean arousal scores were similar after surgery, despite improvements in all other areas including lubrication. However, it has been previously reported that women may be unaware of their genital response, particularly with respect to arousal [8]. It seems that the mechanism of

arousal may be more complex, a phenomenon which is not currently well-understood.

What remains unclear is the mechanism for the improvement in sexual function seen here. While we did not demonstrate a correlation between bladder symptom improvement and sexual function scores, our study is limited by the fact that we did not have other objective criteria to assess symptom improvement. Use of a voiding diary or urinary quality-of-life index would have added strength to our conclusions. Given this, it is possible that improvements in urinary symptoms may be responsible for our documented changes and is a potential confounder of these results. Nevertheless, it is still interesting to note that the patient's subjective impression of voiding symptom improvement was not linked to their sexual function. Thus, it is feasible that the nerve stimulator has a positive impact on sexual function independent of its impact on urinary symptoms.

A further limitation of this study was our small sample size, which may have biased our results. Since many subjects selected for Interstim® are elderly and medically fragile, we found recruitment to be much more difficult than initially anticipated. Moreover, our validated questionnaire only measures sexual function in those that were active 4 weeks before the study, possibly reducing our eligible pool. Our cohort included subjects of various ages, demographic backgrounds, and indications for placement, which may have affected our findings. Finally, we acknowledge that sexual function is complex, and other factors may have led to the improvements seen. Despite these limitations, we feel we have presented interesting information: sacral neuromodulation seems to improve sexual frequency and sexual function scores in subjects with urgency frequency and urge incontinence. Strengths of this study are the prospective design, which limits recall bias, as well as the use of a validated questionnaire. Further research should focus on the recruitment of a larger sample and should involve the use of an objective tool for urinary symptom improvement. Other avenues for future directions include testing the device in subjects presenting for treatment of sexual dysfunction.

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