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QUALITY OF LIFE OF PATIENTS FOLLOWING INTERSTIM SACRAL NERVE MODULATION - A 12 YEAR FOLLOW-UP

Hypothesis / aims of study

Although objective success of sacral nerve modulation (SNM) has been widely documented there are few reports addressing the long-term Quality of Life (QoL) effects of SNM. Several authors have noted increased QoL for patients implanted with SNM devices. However, these studies are limited in their length of follow-up and/or size of their patient population. Our Department is one of the original pioneers of SNM in Canada having first started this unique surgical treatment in 1994. We present QoL outcomes in patients receiving SNM at our centre over the last 12 years.

Study design, materials and methods

We have electronic charts on all patients who have undergone implantation of a sacral nerve stimulator from 1994-2006 at our institution contained in a SNM data base. A validated questionnaire was mailed to each patient. The questionnaire was designed to reveal subjective improvement/worsening of symptoms in patients implanted with a sacral nerve stimulator compared with symptoms prior to its implantation. In addition, patient age and gender, initial diagnosis, date of the sacral nerve implant and a global assessment of their current QoL was ascertained.

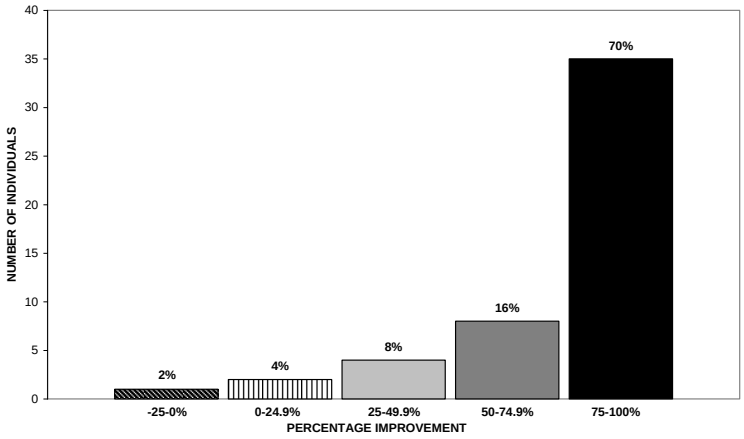
Results

There were 92 consecutive patients identified in the SNM database. Of these individuals, 1 patient had died and 2 had their device explanted. Fifty patients (48 women and 2 men) returned their questionnaires for a return rate of 56.2 %. Mean patient age was 52.16 years. Sacral nerve stimulators were insitu for an average of 51.48 months with a range of 1 to 142 months. The implant had been placed for a variety of conditions including incontinence, voiding dysfunction, OAB and interstitial cystitis.

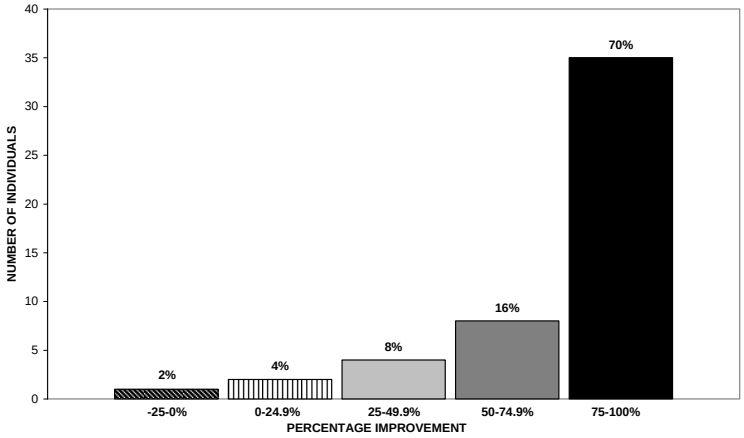
On average patients voided every 3.42 hours during the day and 5.28 hours at night. When questioned regarding urgency 32 (64%) patients could always make it the bathroom while 18 (36%) had occasional difficulty. With regards to incontinence 30 (60%) wore no protection, 12 (24%) wore a small mini pad, 5 (10%) wore a large pad and 1 (2%) wore incontinence briefs.

Compared to pre-operatively 43 (86%) of patients described their urinary system as better, 6 (12%) the same and 1 patient reported worsening of symptoms post SNM placement. Knowing what they know now 94% of patients would have the surgery again and 94% report their urinary control as better than prior to the surgery. Global assessment questions (Figures 1 and 2) revealed almost 70% of patients were greater than 75% improved with regards to QoL and bladder symptomatology.

How Much Impact On Your Quality Of Life Has Occurred With Placement of the Sacral Nerve Stimulator?



How Much Have Your Bladder Symptoms Improved Or Worsened Since The Placement of the Sacral Nerve Stimulator?



Interpretation of results

Our study demonstrates that over the last 12 years our patients have had tremendous improvement in their quality of life secondary to placement of the sacral nerve stimulator. Patients who have had the device implanted up to 142 months are extremely satisfied. Their average voiding patterns simulate normal frequency patterns, very little nocturia and mild incontinence issues. The global assessment questionnaires reveal almost 90% of patients at our centre were at least 50% improved in regards to quality of life and bladder symptomatology. Given the positive effects on QoL with SNM it is not surprising that over 90% of patients would have the surgery again knowing what they know now. In addition it appears that the device continues to be successful long term in improving QoL and voiding symptomatology. This is an excellent response for voiding disorders that are notoriously difficult to treat and have a well documented detrimental effect on patient's quality of life.

Concluding message

This is one of the first long term studies to adequately assess the impact of sacral nerve modulation on patient's quality of life. This study demonstrates the tremendous positive effect SNM has with over 70% of our patients showing greater than a 75% improvement in quality of life parameters over the last 12 years.

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Capital Health Research Ethics Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**