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Research Article

Sacral Nerve Stimulation for Neurogenic Bladder: Our Experience

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Abstract

Introduction: Neurogenic bladder is a condition causing significant effect on the quality of life of the patient. Sacral nerve stimulation (SNM) has a good role in these patients. We report our experience with sacral neuromodulation.

Methods: 15 patients with refractory urinary bladder were included in this study. The aetiology of the neurogenic bladder included 7 spinal cord injury, 3 meningomyelocele, 2 failed back surgery syndromes, two multiple sclerosis and one mixed bowel/bladder (aetiology unknown). All 15 underwent test stimulation.

Results: Only 10 out the 15 had a positive trial and proceeded to the next stage of implantation. The 3 patients with failed trial were all patients with complete cord injury or injuries below T12 (vertebral level) and more than 8 years duration. Of the other two one was a meningomyelocele and other was a case of advanced multiple sclerosis. Follow up period was upto four years; all 10 patients doing well. One of early cases had lead migration and had to be repositioned. One patient used to develop shock like sensation in perineum; the stimulation was stopped for six weeks and restarted at lower frequency.

Conclusion: SNM is a very effective therapy for neurologic bladder in selected patients. Detailed preoperative assessments and trial are very important in this selection.

Keywords: Sacral Nerve; Neurogenic Bladder; Stimulation; Results

Introduction

Neurogenic bladder is a disorder of the lower urinary tract created by damage to or diseases of the nervous system. The disorder can also create substantial embarrassment resulting in social isolation for affected patients causing significant effects on quality of life [1]. Many treatments are available for the treatment of neurogenic bladders. However, these are not effective in some patients. Many patients experience concurrent bowel problems and chronic pelvic pain, which also must be addressed simultaneously [2]. Sacral nerve stimulation is an internationally accepted technique for neurogenic bladder especially when the first line treatment methods fail. In this article we analyse our experience with this treatment modality.

Materials and Methods

A group of fifteen patients underwent trial sacral nerve stimulation for neurogenic bladder of various aetiology. The aetiology included seven patients with spinal cord injury, 3 patients with old operated meningomyelocele, 2 were cases of failed back surgery syndrome, two had multiple sclerosis and one mixed bowel/bladder involvement of unknown aetiology. All patients were taken up after complete urodynamic studies.

The trial procedure was done under local anaesthesia. First the patient was asked to keep a voiding diary for five days and the trial was done on the sixth day. The voiding diary used was the one described by the Urology department of the University of California,

Los Angeles. (http://urology.ucla.edu/workfiles/Pelvic_Medicine/Voiding_Diary_Instructions.pdf). Trial is done under local anaesthesia and C-arm control. The S3 foramen is identified using the C-arm and the curvature of the sacral notch. The trial was done using the Interstim II system (Medtronic). The electrode is stimulated and the responses were noted. Responses signalling correct placement include bellows contraction of the pelvic floor, the patient experiencing tingling of the perineal and perianal regions and plantar flexion of the great toe. These observations are important to confirm the integrity of the neural pathways. The voiding diary is again continued as before for five days. After that the patients' impressions and a comparison of the voiding diary is done to see if the trial is positive. If there is an improvement of 50% in both objective and subjective parameters, the permanent set (Interstim II- Medtronic) was implanted. Bilateral trial and implantation was always used on the assumption that one side will always work especially in case of lead migration. Also for cutting costs the permanent implant was always used for the trial.

Results

A total of 15 patients were taken up for the trial procedure. Sensory and motor responses were checked during the intraoperative trial stimulation. Good motor response was always taken as positive. Ten out of these fifteen patients had a positive trial and went to permanent implantation. One patient with failed trail was an old operated meningomyelocele. She did not have any sensation of the trial and the voiding diary was not different. Another lady was a very advanced multiple sclerosis and did not survive long. The other three failed trial patients were those with spinal cord injuries. One had a complete cervical cord injury with quadriplegia, one had cord injury below T12 levels (flaccid paraplegia) and third had a thoracic incomplete cord injury. All these patients had the spinal cord injury of more than 8 years. All the ten patients have been followed up upto four years: all 10 patients are doing well. One of the early cases had lead migration and this had to be repositioned. Another patient used to develop shock like sensation in the perineum. The stimulation was stopped for six weeks and then restarted at lower frequency to reach higher currents over two months. This time the device worked well and no shock sensations were felt. Of the ten patients six had an overactive bladder with incontinence and three had retention and one had double retention with constipation and diverticular disease. All patients had improvement ranging from 50% to 90%. One patient with retention (meningomyelocele) used to have preoperative creatinine values always above 4 mg%. By six months of surgery, her creatinine reduced and continues to be around 1.6 to 1.8 mg% (2015 to date). One patient did well for upto two years but then started getting painful shocks onto the scrotum. He insisted on explanation which was done.

Discussion

Sacral neuromodulation (SNM) has been approved the U.S. FDA for treatment of refractory voiding dysfunction, urge incontinence, urgency-frequency syndrome and idiopathic non-obstructive urinary retention [1]. Through this article we intend to share our experience about this procedure in India.

Ginsberg [2] published a note on the epidemiology and pathophysiology of neurogenic bladder. The article defined neurogenic bladder as a disorder of the lower urinary tract created by damage to or diseases of the nervous system. The cause may include neurologic disorders, including multiple sclerosis, Parkinson's disease, spinal cord injury, and spina bifida. Neurogenic bladder can lead to urinary incontinence, frequency, and urgency, along with risk for infection and involvement of the upper urinary tract and kidney disease. It also causes substantial social embarrassment.

Campbell and coworkers [3] evaluated treatment satisfaction and compliance with pharmacologic therapy in 1447 urinary incontinence patients. White females were predominant with a mean age of 56 years. Overall, 25% reported being somewhat or very dissatisfied with treatment. Discontinuation of drug treatment was reported by 45% of study subjects, with major reasons being poor efficacy, side effects, and cost. Scheepens., *et al*. [4] looked at the predictive factors for sacral neuromodulation in chronic lower urinary tract dysfunction. Out of 211 patients, 85 had a positive trial. They found that intervertebral disk prolapse, duration of complaints, neurogenic bladder dysfunction, and urge incontinence were found to be significant predictive factors. The Ontario Health Technology Assessment Series [5] assessed the effectiveness, safety, and cost of sacral nerve stimulation (SNS) to treat urinary urge incontinence, urgency-frequency, urinary retention, and faecal incontinence. They concluded that there is level 2 evidence to support the effectiveness of SNS to treat people with urge incontinence, urgency-frequency, or urinary retention. To qualify for SNS, patients must be refractory to behaviour and drug therapy and have had a successful test stimulation before implantation. Successful test stimulation is defined by a 50% or greater improvement in voiding

function based on the results of a voiding diary. Patients with stress incontinence and urinary retention due to obstruction are ineligible for sacral nerve stimulation.

Vignes, Seze and others [6] looked at both clinical as well as financial aspects of sacral nerve stimulation. This technique is indicated in idiopathic bladder overactivity, idiopathic chronic retention and chronic pelvic pain syndrome. More than 75% of patients showed clinically significant response with 50% or more reduction in the frequency of incontinent episodes. From the economic point of view, the initial investment in the device is amortized in the midterm by savings related to lower urinary tract dysfunction.

A trial stimulation using a percutaneous electrode is now always done. Seivert., *et al*. [7] described that tunnelling the trial electrode for a short distance helped to perform percutaneous nerve evaluation (PNE) more effectively with an objective, reliable and less expensive outcome. Because the costs of therapy are not covered by health insurance in all countries, there is a need for an effective and inexpensive way to test and select patients appropriately. The tunnelled electrode maintains its place during the entire test duration. This technique can be performed on an outpatient basis to evaluate sacral nerve modulation.

There has been some discussions on whether stimulation should be bilateral or unilateral. We always have used bilateral trial and stimulation as we expect atleast one side to be in position and function well. Scheepens and colleagues [8] compared unilateral versus bilateral sacral neuromodulation in patients with chronic voiding dysfunction. They had lead migration in upto 25% of cases. They concluded that bilateral stimulation is not superior to unilateral. In some individuals bilateral stimulation may be more effective in relieving symptoms. So, they recommended that if unilateral percutaneous nerve evaluation fails, a bilateral test should be considered. However, Seif., *et al*. [9] differed from this opinion. They did bilateral test stimulation in 62 patients. They concluded that bilateral PNE test stimulation with side-specific amplitude adjustment and the use of advanced PNE electrodes led to a positive PNE result in a good number of patients. This is a substantially increased response rate compared to previous studies. Of the diagnostics groups, the group with neurogenic bladder dysfunctions showed the highest response rate. Another study [10] evaluated if there is a difference in long-term outcomes between patients screened with percutaneous nerve evaluation and a first stage tined lead procedure. It was found that 46% of patients screened with percutaneous nerve evaluation met the criteria for permanent implantation whereas it was 69% for those who underwent direct screening with the tined lead procedure permanent stimulators were placed. Moreover, patients in whom percutaneous nerve evaluation failed subsequently underwent screening with tined lead procedure 44% were implanted with a neurostimulator after a successful response. The first stage tined lead procedure is a more sensitive screening tool than percutaneous nerve evaluation but long-term success seems to be independent of the screening method. Patients in whom percutaneous nerve evaluation initially failed but who responded to prolonged screening with tined lead procedure appeared to be as successful as those who directly responded to percutaneous nerve evaluation or the tined lead procedure. A similar study was done in 100 patients by Leong and coworkers [11]. The response after 1st stage tined-lead placement test was better in females and younger patients. They concluded that 1st stage tined-lead placement test may be a more sensitive screening method than PNE to identify patients eligible for SNM therapy. It is based on these studies as well as the fact that costs of the surgery can be brought done that we now routinely use the first stage directly as a screening procedure.

Leroi., *et al*. [12] assessed the outcome and cost analysis of SNM compared to alternative medical and surgical treatments in 369 patients with incontinence. SNM significantly improved the continence status and quality of life of patients with urge urinary and/or faecal incontinence compared to alternative treatments. It is also a cost-effective treatment for urge urinary and/or faecal incontinence. Infact Thompson, Sutherland and Seigel [1] argued that with these advances the pool of patients who will benefit from SNM will expand over time. The tined lead allows for placement and stimulation to be performed in the outpatient setting under local anaesthesia with mild sedation. Lead migration has been minimal and efficacy improved. The use of fluoroscopy has improved accuracy of lead placement and has led to renewed interest in bilateral percutaneous nerve evaluation (PNE). Bilateral PNE can be performed in the office setting under local anaesthesia, making a trial of therapy less expensive and more attractive to patients. A smaller IPG has not only improved cosmesis, but decreased local discomfort and need for revision.

Routinely X rays are done in the immediate postoperative period for documenting the position of the electrodes and also as baseline during followup. A study was done by Gahzi, Banakhar, El-

terman and Hassouna [13] to determine whether the radiographic position of the electrode in the sacral foramen predicted the long-term outcome of SNM therapy. A total of 69 patients (61 female and 8 male patients) were included with a median age of 55 years. This study did not show a correlation between the long-term response to SNM and the electrode position on follow-up sacral x-rays.

Lay and Das [14] reviewed the use of SNM in neurogenic overactive bladder (OAB). The procedure is minimally invasive and is effective in about 70% of patients who have a permanent system. Similar success rates have been observed in patients with neurogenic OAB. SNM has been used successfully in selected patient population with good results. Sukhu, Kennelly and Kurpad [15] reviewed the current trends in overactive bladder. Studies have demonstrated that it is an effective treatment for OAB and urge incontinence as indicated by decreased number of voids, increased bladder capacity, and fewer leakage events. In addition, the effects have proved to be durable to multiple years following implantation. These benefits come at the expense of a high rate of adverse events, although with comparable long-term cost-effectiveness to botulinum toxin A. Bartley, Gilleran and Peters [16] also opined that neuromodulation has revolutionized the management of OAB and is now well established as a safe and effective treatment for those refractory to conservative treatments. It is an attractive option owing to its minimally invasive approach, tolerability, positive outcomes and reversibility.

Gani and Hennessey [17] tried to provide a review of the diagnosis and different surgical treatment options for underactive bladder (UAB)/detrusor underactivity (DU). DU affects up to 45% of men and women > 70 years of age. The symptoms of DU overlap significantly with overactive bladder (OAB) and bladder outlet obstruction (BOO). Urodynamic findings include low voiding pressure combined with slow intermittent flow and incomplete bladder emptying. Non-operative management for DU is acceptable. SNM provides excellent outcomes for DU, but patient selection is important. Similarly, Mehmood and Altaweel [18] looked at the long-term outcome of sacral neuromodulation in 27 patients with idiopathic nonobstructive urinary retention. 88.8% of patients demonstrated a > 50% improvement in symptoms and underwent permanent device placement. At followup of upto 9 years, 83.3% patients demonstrated sustained improvement rates of > 50%. Four (16.6%) had their device explanted. Ten (41.6%) of the 24 patients underwent surgical revision. Most of the adverse events were managed by device reprograming. The conclusion was that SNM is a highly effective and safe procedure in this subset of the female population with idiopathic refractory nonobstructive urinary retention. Cardarelli., *et al*. [19] retrospectively looked at 157 patients who underwent sacral neuromodulation in four centres in Italy. Patients with overactive bladder had a significant reduction of incontinence episodes, and nocturnal micturitions. Those with retention had reduction in the mean post- voiding residual volume and number of self-catheterization. This study confirmed effectiveness of sacral neuromodulation in the treatment of refractory overactive bladder syndrome and urinary retention, showing high cure rates and low complication rates.

White and coworkers [20] examined incidence and predictors of complications with sacral nerve stimulation in 221 patients. 67 patients (30.3%) had experienced some adverse effects (AE). The significant predictors of AEs included a history of trauma, a change in body mass index class, enrollment in a pain clinic, the duration of follow-up and a history of AEs. They concluded that SNM is an effective treatment for patients with intractable voiding dysfunction. Complications are not uncommon but can be minimized with better patient selection. Leong., *et al*. [21] looked at satisfaction and patient experience with sacral neuromodulation through a postal questionnaire. Overall satisfaction with sacral neuromodulation was high at 90%. No correlations were found between the satisfaction and age, gender, complaint type, sexual dysfunction or therapy duration. 56% of patients reported side effects; of these 89% of these patients did not seek further therapy. Of patients with additional defecation problems 47% experienced relief of complaints.

Faecal incontinence and urinary incontinence are common and often associated. So Chodez., *et al*. [22] looked at patients who had double incontinence after sacral neuromodulation. Improved faecal incontinence was observed in 44 - 100% of cases, while improved urinary incontinence was observed in 20 - 100% of cases. Patient satisfaction with the correction of double incontinence, both anal and urinary, was highly variable, ranging from 20 to 100%. So, in cases of double incontinence sacral neuromodulation should be the treatment of choice.

Conclusion

Sacral nerve stimulation has a good role in selected Indian patients. Strict criteria applied during the preoperative assessments and managing the expectations of the patients are very important for a good long term effect.

Conflict of Interest

No financial interest and no conflict of interest exists.

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