

Sacral Nerve Stimulation (Neuromodulation) for the Treatment of Lower Urinary Tract Symptoms in Adult Patients

Sacral nerve stimulation (SNS) has become established in recent years as a treatment option for two groups of patients seen within urological practice. Firstly, it can be used for patients with idiopathic detrusor over-activity leading to symptoms of urinary frequency, urgency and urge incontinence.¹ The second group are women with urinary retention due to either an unknown cause or abnormalities of the distal urethral sphincter (Fowler's syndrome). Other indications are now being evaluated as interest and research into this exciting treatment modality gains momentum.

Origins of the technique

Electrical stimulation of the peripheral nervous system has long been known to influence lower urinary tract symptoms (LUTS) and perception of pelvic pain, whether delivered transcutaneously or by implanted devices. Historically, stimulation has been applied using anal, vaginal, bladder wall and cutaneous electrodes. In the modern era, anal and vaginal stimulation probes have been used to treat stress incontinence, while transcutaneous electrical nerve stimulation (TENS) has been successfully used to treat chronic pain. While treating such patients, investigators observed that electrical stimulation also had a beneficial effect on urinary urgency and urge incontinence.^{2,3} Both anogenital and transcutaneous stimulation techniques have since been used to treat bladder overactivity. However, the short hang-over effect, combined with the intensity of the treatment schedules themselves, have prevented widespread acceptance of these non-invasive techniques.

A more invasive approach using direct electrical stimulation of the third (and sometimes fourth) sacral nerves was first described experimentally in 1988⁴ and is now the most prominent and well established of the so-called neuromodulation techniques. In contrast to the non-invasive methods, sacral nerve neuromodulation uses continuous stimulation and close nerve contact. This requires surgical implantation of a pulse generator and electrode.

Theoretical basis of sacral neuromodulation

The aim of sacral neuromodulation is to relieve bladder symptoms by rebalancing micturition control. However, the exact neurophysiological basis for this action is still unclear. Everyday clinical experience shows that bladder contractions can be suppressed by external sphincter and pelvic floor contractions, and therefore it is not surprising that electrical stimulation of the sacral nerves causes bladder inhibition in both animals and man.^{2,5} However, when mixed S3 nerves are stimulated at the level of the sacral foramina it is not always clear whether therapeutic neuromodulation is the result of direct activation of the sensory nerves, or indirectly by activation of the striated external sphincter and pelvic floor muscles leading to reflex detrusor relaxation. Both mechanisms have been considered and researchers now conclude that it is the afferent pathways, causing inhibition at either spinal or supraspinal level, which play the crucial role.⁶⁻⁸ The most direct evidence supporting an afferent mechanism comes from the fact that neuromodulation effects can be demonstrated with stimulation of the (purely sensory) dorsal penile and clitoral nerves.²

Indications

The main indications for SNS are detrusor overactivity and female urinary retention as mentioned above.

However, there is also some evidence that neuromodulation may be useful in patients with voiding disorders of neurological origin: it has been used successfully in patients with multiple sclerosis and incomplete spinal cord lesions.^{9,10} However, the numbers of such reported cases are small. Painful bladder disorders, notably interstitial cystitis, have also been studied in small case series with some, but not all, investigators finding favourable responses.¹¹

S3 sacral neuromodulation received FDA approval in the USA for the treatment of urge incontinence in 1997 and for urgency/frequency and non-obstructive urinary retention in 1999. However, within the UK current National Institute for Clinical Excellence (NICE) guidelines exist only for patients with urge/frequency syndrome and urge incontinence.¹

Pre-operative patient work-up

All patients who are considered for sacral neuromodulation should have their diagnosis defined as clearly as possible by urodynamic assessment. They should have undergone rigorous trials of conservative treatments such as lifestyle modification, pelvic floor exercises and anticholinergic therapy. It is also important to document the severity of patient symptoms using frequency/volume charts which document fluid intake and urine output over several days.

Not every patient will gain benefit from sacral neuromodulation and it is now accepted practice that every patient considered for this technique should undergo a trial period of temporary stimulation known as percutaneous nerve evaluation (PNE). The test electrode is placed in either the right or left S3 posterior sacral foramen using local anaesthesia. Surface markings identify the site of the posterior sacral foramen and a hollow needle is used to allow the electrode to be threaded into position. Correct positioning of the electrode is determined by both motor and sensory responses. Once well positioned, the temporary electrode is held in place with an adhesive dressing and an external pulse generator provides stimulation for three to five days. The patient provides subjective information regarding their response to the PNE, while objective data comes from accurately completed frequency/volume charts.

Only those patients who gain significant benefit from the PNE proceed to neuromodulator implantation. The PNE is generally considered successful when there is at least 50% improvement in the main voiding symptom. Although results vary between studies in the literature in general approximately 50% of patients will respond well to the trial stimulation and go on to receive a definitive sacral neuromodulator implant.

The implant technique

Implantation of a sacral neuromodulator is performed under either general or local anaesthesia. The original open surgical approach to the sacrum¹² has been superseded by a minimally invasive percutaneous alternative.¹³ A quad electrode with four independent stimulation electrodes is positioned under radiological control. Once in place, an outer sheath is removed and plastic tines spring out and fix the assembly in place (Figure 1). The electrode is tunneled to a subcutaneous pocket in the upper outer quadrant of the buttock area where the pulse generator is implanted (Figure 2).



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Fig 1a

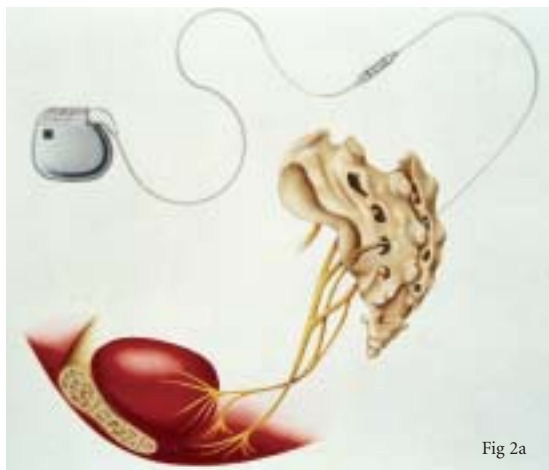


Fig 2a



Fig 1b

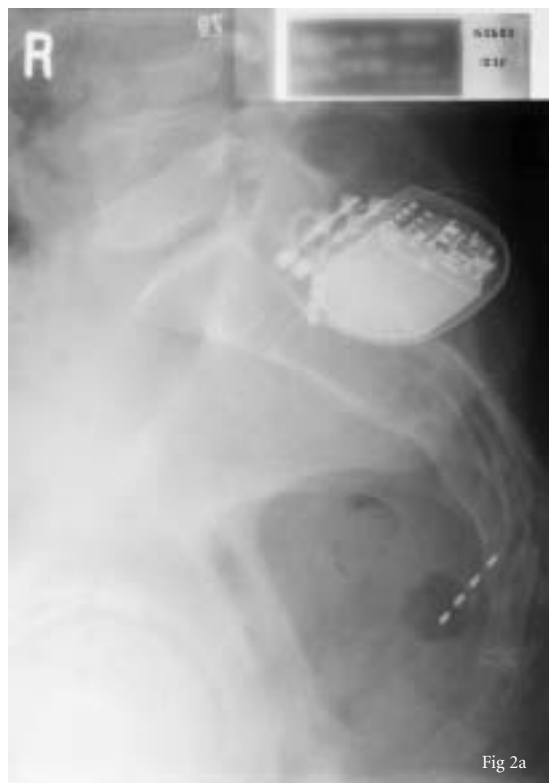


Fig 2a

Figure 1. (a) The tined lead.
(b) X-ray showing the tined lead in position.

Figure 2: (a)The sacral neuromodulation circuit.
(b) X-ray showing the neuromodulation circuit in situ.

A key feature of the technology is that the pulse generator can be adjusted using an external computer and telemetry link. The system is extremely flexible and familiarity with its options and capabilities is essential; successful initial programming and subsequent adjustment is critical to the success of an implant programme.

Results and complications

Efficacy data from both randomised controlled trials and case series studies show that about 70% of the patients who received sacral neuromodulators for urge/frequency and urge incontinence became dry or showed improvement in their main incontinence symptoms.^{1,14-16} This compared with 4% in the control groups in randomised studies. Fewer episodes of leakage, fewer pads used and fewer voids per day were also reported post-implantation. The data concerning female patients with non-obstructive urinary retention are less extensive but shows that 69% eliminated catheterisation at six months and a further 14% had a 50% or greater reduction in the catheter volume per catheterisation.¹⁷

There is no evidence that the safety profile for sacral neuromodulation differs according to patients' clinical indica-

tions for implantation. Overall surgical revision rate is approximately 33%. The most common complications are pain (24%), lead migration (16%), wound problems (7%), adverse effect on bowel function (6%), infection (5%), and generator problems (5%). 15% of patients require replacement or relocation of the implanted pulse generator and some (9%) have required permanent explantation.¹

Over the past eight years 55 patients with a variety of lower urinary tract dysfunctions have received permanent SNS implants at our centre. Our experience in these patients largely mirrors that reported in the literature, although we believe that medium and long-term benefit will be achieved in about 60% of patients if one is dealing with highly symptomatic subjects. One of the major problems that we encounter is that there is a group of patients whose symptoms return within the first few months after implantation; this relapse occurs despite the system continuing to produce typical sensory and motor responses for S3 stimulation and is resistant to reprogramming efforts. It is our belief that this picture represents central nervous system adaptation to the stimulus and this might be analogous to the loss of efficacy that can be seen when neural stimulators are used to treat chronic pain.

Conclusion

Sacral neuromodulation is an exciting and valuable technique which has the ability to transform the quality of life of some patients with severe LUTS which are refractory to more conservative measures. The simplicity of the surgical technique and its associated safety are key issues for patients who are considering this form of treatment and set it apart from alternative approaches such as augmentation cystoplasty. The widespread adoption of SNS in the UK remains hampered by funding and cost issues (each implant costs in the order of £6,750). However, we feel

that its proven utility and the lack of acceptable alternative treatment options should lead to the establishment of regional centres which would provide a neuromodulation implant service.

There is every indication that neural stimulation will become an important modality in the treatment of some patients with LUTS. However, future research and technological developments are likely to demonstrate that current practice will come to be seen as the beginning of an era rather than the definitive delivery of this form of therapy.

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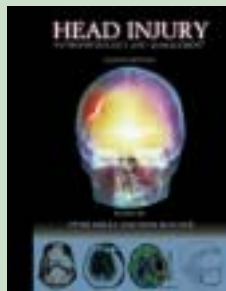
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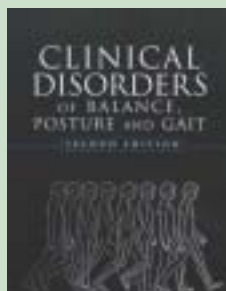
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