Sacral nerve stimulation

Summary

Background. Sacral nerve stimulation involves electrical stimulation of a sacral nerve root by means of an electrode and a stimulator. In the course of just a few years, sacral nerve stimulation has become a treatment option for selected patients with urinary retention, urinary incontinence, anal incontinence and constipation. The method is also being tested in connection with several other indications.

Material and methods. The article presents the method and reviews the results of treatment in connection with various indications on the basis of the authors' own experience and after a non-systematic PubMed search.

Results. An external stimulator is used during a test period of 3–30 days, depending on the indication. A positive test (improvement of symptoms by 50 % or more) is achieved by 70–90 % of patients with anal incontinence, 70 % with non-obstructive urinary retention, 52–77 % with urinary urge incontinence and 43–72 % with constipation. Sacral nerve stimulation may also be efficacious in patients with chronic pelvic pain. Following implantation of a stimulator a sustained effect is seen in 50–90 % of patients with a positive test response. Up to 75 % of patients will need repeated follow-up in the form of stimulator reprogramming or reoperation due to technical failure. The service life of the stimulator is 3–10 years, and it must be replaced surgically when the battery wears out.

Interpretation. Treatment with sacral nerve stimulation may have a sustained effect in patients with various pelvic floor dysfunctions, and appears to be especially efficacious in cases of anal incontinence and non-obstructive urinary retention. Most of the patients will need close follow-up in order to maintain an optimal result.

Stig Norderval*
stig.norderval@unn.no
Mona Rydningen
Department of Gastroenterological Surgery
and
Norwegian Continence and Pelvic Floor Centre
University Hospital of North Norway

Rolv-Ole Lindsetmo
Department of Gastroenterological Surgery
and
Norwegian Continence and Pelvic Floor Centre
University Hospital of North Norway
and
Institute for Clinical Medicine
University of Tromsø

Dag Lein
Department of Urology and Endocrine Surgery
and
Norwegian Continence and Pelvic Floor Centre
University Hospital of North Norway

Bathold Vonen
Department of Gastroenterological Surgery
and
Norwegian Continence and Pelvic Floor Centre
University Hospital of North Norway
and
Institute for Clinical Medicine
University of Tromsø

* Temporary address:
Level 3, Suite 2
41 Victoria Parade
Fitzroy, VIC 3065, Australia

Permanent electrical stimulation of sacral nerve roots, sacral nerve stimulation (SNS), was first used in the late 1970s by Brindley et al. to treat neurogenic urinary retention (1). Just over ten years later, the first patient series showing positive results from the treatment of this patient group became available (1, 2). The first report on the effect of sacral nerve stimulation in three patients with faecal incontinence was published in 1995 (3).

In 1999, this method was introduced in the University Hospital of North Norway, the first Nordic hospital to do so. Sacral nerve stimulation is now used to treat a number of dysfunctions of the lower urinary tract, the pelvic floor and the bowel, and new indications are being tested. The method is minimally invasive and does not cause any structural changes in the pelvic floor. Even though sacral nerve stimulation is established throughout Norway today, it is our impression that the method is relatively little known in the primary health services, and not even very well known in the specialist health services.

Materials and methods

The article reviews sacral nerve stimulation and treatment results for various indications based on the authors' own experiences of the method and a review of relevant literature retrieved by way of a non-systematic PubMed search. All the authors of this article perform sacral nerve stimulation at University Hospital of North Norway, and they also participate in the interdisciplinary working group at the Norwegian Continence and Pelvic Floor Centre.

Mechanism

Electrical stimulation is obtained by placing an electrode attached to a stimulator against one of the sacral nerve roots (fig. 1). The voltage used normally ranges from 0.5 to 3 volts, with a frequency of approximately 15 Hz. The effect was initially assumed to be caused by direct stimulation of the bladder muscle, the urethral sphincter and the anal sphincter via motor nerves (3, 4). Later studies, however, indicate that electrical stimulation of the sacral nerve roots causes complex modulation of motor, sensory and autonomous nerve paths in both the central and the peripheral nervous system (5–7). The complexity of this active mechanism is the most likely reason why the method can have an effect on several partly conflicting processes.

Surgical procedure

Currently, only one system for sacral nerve stimulation is commercially available (InterStim, Medtronic, Minneapolis, MS). The surgical procedures are identical irrespective of the indication in question. First, a peripheral nerve evaluation test (PNE test) is undertaken to establish whether the patient will benefit

Main message

- Sacral nerve stimulation is low-voltage electrical stimulation of a sacral nerve root. Sacral nerve stimulation may be efficacious in treating anal incontinence, various urinary dysfunctions and constipation.
- A permanent stimulator is implanted only when a test period has demonstrated clear efficacy.
- Patients with a sacral nerve stimulator will need specialized and ready available follow-up.

from sacral nerve stimulation. Under general anaesthesia, sedation or local anaesthesia one or several sacral foramina are cannulated, usually foramen 3 or foramen 4. When the cannula is inserted through the sacral foramen, the tip will be located immediately adjacent to the corresponding sacral nerve root (fig. 2).

The cannula is supplied with pulsating current from a stimulator. If the operation takes place under general anaesthesia or sedation, the stimulation may lead to contraction of the anal sphincter (fig. 3). If it takes place under local anaesthesia, the stimulation may also cause a sensory response corresponding to the rectum, the bladder or the vagina. If an appropriate response is obtained, an electrode is inserted in the same place using percutaneous technique.

The electrode is linked to an external stimulator that the patient carries during the test period. The duration of this period depends on the patient's condition. During the test period, the patient keeps a daily record of the frequency of the symptoms. If the test is carried out using a temporary electrode, this can be easily removed by the patient him/herself once the test period is over. If a permanent electrode has been used, the extension wire emerging through the skin at the flank can be cut at the skin level.

After completion of the test, the frequency of the symptoms prior to and during the test are compared. There is a broad agreement that a PNE test should lead to a reduction in symptoms of 50 % or more before implantation of a permanent stimulator is offered.

Two different stimulators are available – one with a service life of up to ten years and another, considerably smaller model, with a service life of 3–5 years. The stimulator is implanted deeply subcutaneously in the left or right buttock, according to the patient's wishes (fig. 4). If the patient was tested using a temporary electrode, a permanent electrode is inserted during the implantation of the stimulator. If a permanent electrode was used for the test, the stimulator will be attached to this electrode. Patients are supplied with a remote control device that enables them to turn the stimulator on and off, change the voltage and switch between up to four different stimulation programmes.

Patient selection

Implantation must not be undertaken if there is a skin infection in the area, and a special evaluation must be made if the patient suffers from chronic inflammation of the skin (e.g. psoriasis) or has a weakened immune system. Care should also be taken with regard to persons with personality disorders, since they more often respond poorly in spite of a positive test period (8). In our experience, patients need to be highly motivated to undergo sacral nerve stimulation, and preferably be able to handle the remote control device that controls the stimulator. Furthermore, it is essential that the patients have realistic expectations regarding the results of the treatment, including the possibility of a technical failure and the need for stimulator reprogramming and possibly reoperation.

It has been assumed that persons who are likely to need an MR scan of the pelvic floor region later are not suitable subjects for sacral nerve stimulation. However, studies have failed to establish clearly any undesirable effects for the patients following MR scans (9, 10). This is also our own experience. However, a recent study reports that two patients had their stimulators damaged as a consequence of MR scanning of the pelvic region using a 3-tesla scanner (11). The necessity of an MR scan should therefore be balanced against the risk of damaging the stimulator.

Indications and results

Non-obstructive urinary retention

The first patients who were treated with sacral nerve stimulation suffered from neurogenic urinary retention (partial transverse lesion, multiple sclerosis and stroke) (1, 2). Sacral nerve stimulation can also be efficacious in cases of neurogenic urinary retention due to cauda equina syndrome, prolapse of the intervertebral disc, sequelae after spinal surgery and polyneuropathy (12). The treatment can also be efficacious in cases of idiopathic, non-obstructive urinary retention where other forms of treatment have failed (5, 12, 13).

A positive PNE test response is achieved in approximately 70 % of patients (14), after a test period of 3–7 days. Patients with a positive test response achieve a significant reduction of residual urine and use of a catheter once the stimulator is implanted (5, 13). Some studies also show a significant improvement in perceived health (5), health-related quality of life and depression score (15). Other studies have been unable to establish such correlations (13). A total of 50 %–80 % of those who have a stimulator implanted are experiencing a beneficial effect 3–6 years after the implantation (12–14).

Urinary urge incontinence

Urinary urge incontinence is characterized by bouts of a strong and irresistible urge to urinate without the bladder being full. The syndrome may also be accompanied by occasional incontinence (urge incontinence). The condition is initially treated with bladder training and antimuscarinic drugs (16). If this treatment has little effect, sacral nerve stimulation can be attempted.

Sacral nerve stimulation may also be efficacious, irrespective of whether any hyperactivity of the detrusor is detectable or not, in patients both with and without accompanying urinary incontinence (17). A positive PNE test response is achieved in 52 %–77 % of the patients (18) after a test period of 3–7 days. In patients who have a stimulator implanted, the effect is sustained in approximately 60 % after 5–6 years (12, 13).

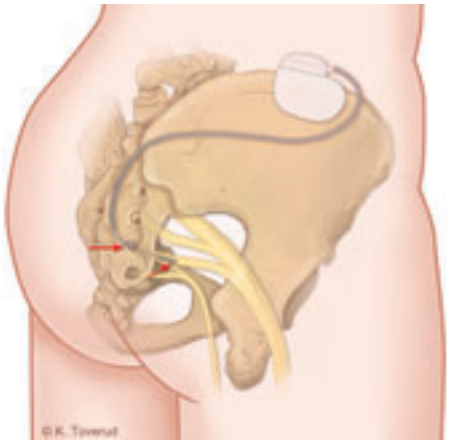

Figure 1: *Schematic drawing of a woman's sacrum and pelvis, posterior view. The nerve electrode has been inserted through the third sacral foramen on the right side (solid arrow). The electrode is ideally placed against the third sacral nerve (stippled arrow). The stimulator is placed deeply subcutaneously, and can be seen projected over the right iliac crest.*

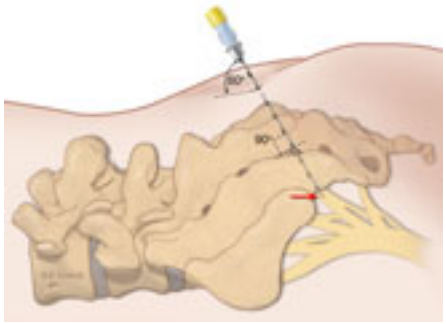

Figure 2: *Schematic drawing of cannulation of the third sacral foramen on the left side. The tip of the cannula (arrow) will ideally be placed against the corresponding sacral nerve when the cannula is inserted at an angle of 60° to the skin over the sacrum.*

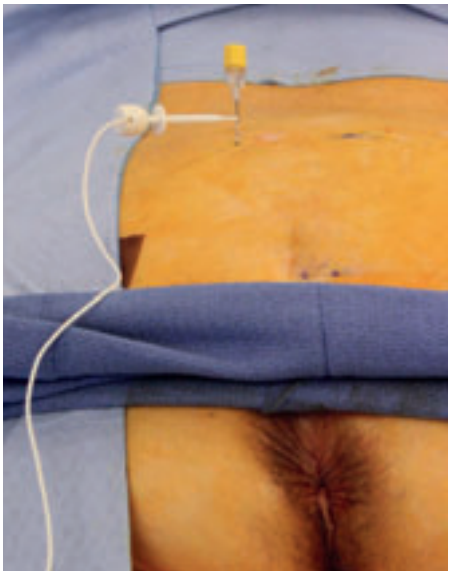

Figure 3: *A cannula has been placed in the third sacral foramen on the left side. The cannula is attached to an electrical cable to test the motoric response of the anal sphincter. Photo: Stig Norderval. The patient has consented to publication of the picture.*

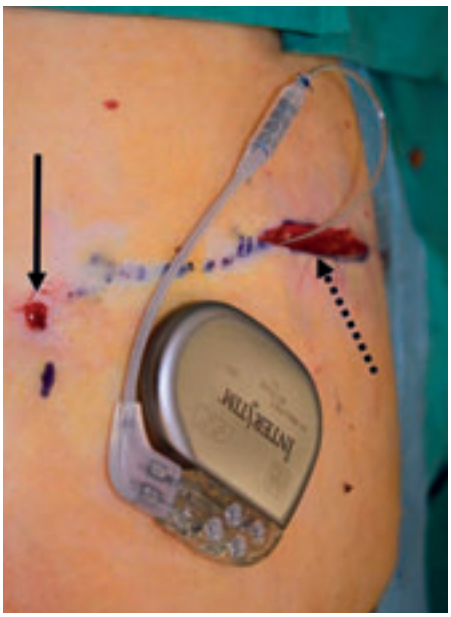

Figure 4: *A permanent stimulator attached to an electrode which has been tunnelled subcutaneously from the third sacral foramen on the right side (arrow) to an established subcutaneous pocket on the right side (stippled arrow). The stimulator is ready to be implanted in the subcutaneous pocket. Photo: Stig Norderval. The patient has consented to publication of the picture.*

Anal incontinence

Sacral nerve stimulation can be indicated in patients with faecal incontinence or gas incontinence combined with an inability to retain faeces when they experience an urge («urgency»), in cases where maximally conservative treatment has been ineffective. The PNE test is conducted over a period of 2–3 weeks. A positive test response is achieved for 70 %–90 % of patients (19–22). In those who have an implanted stimulator, the effect is sustained in 70 %–90 % after 2–5 years (19, 22, 23). Double-blind studies with the stimulator set so that patients were unable to determine whether it was turned on or off have shown that symptoms recur when the stimulator is turned off (24, 25).

The treatment has a positive cost-benefit effect, with a significant improvement in quality of life (26, 27). Patients with sphincter lesions covering up to one-third of the circumference can benefit from sacral nerve stimulation (20). However, sphincter lesions detected by ultrasound are a negative predictor of success (28), and large sphincter defects should probably first be treated by way of sphincter reconstruction.

Constipation

The documentation on the effects of sacral nerve stimulation on chronic constipation is more limited than for the conditions described above. Stimulation of the right or left third sacral nerve root has been shown to increase motility in the left colon and in the rectum (29). An effect has been found in patients suffering from intractable voiding dysfunction with normal and prolonged passage time (30, 31). The PNE test is undertaken over a period of 3–4 weeks. A positive PNE test response in cases of chronic constipation is achieved in 43 %–73 % of patients (30, 32), and the effect is sustained in approximately 90 % after two years (30, 31). A double-blind study with the stimulator set so that patients were unable to determine whether it was turned on or off have shown that symptoms recur when the stimulator is turned off (33).

Other conditions

Sacral nerve stimulation may have an effect on chronic pelvic floor pains, for which all other available treatments have been attempted (34, 35). In a study of nine patients suffering from chronic pains in the anus or rectum, a positive PNE response was obtained for four patients. The median VAS pain score was reduced from 8 to 1, with a sustained effect for more than two years after the implantation of a permanent stimulator (36).

A pilot study has shown that sacral nerve stimulation can be efficacious in patients who are considerably distressed by irritable bowel syndrome (37), and a research group in Århus, Denmark, is currently investigating this in a prospective study.

Sacral nerve stimulation has also been attempted on patients who are at an acute stage after a transverse lesion. Bilateral permanent stimulation may also be efficacious in achieving voiding of the bladder and preventing development of neurogenic bladder dysfunction and motility dysfunction of the colon (38). If this is confirmed, sacral nerve stimulation may be implemented in the early treatment plan for patients with a transverse lesion.

Complications

After implantation, an infection develops in 2 %–10 % of the patients (19, 39) and leads to removal of the implant in approximately half of the cases. Other complications include pain radiating to the perineum or a lower extremity, pain or discomfort around the stimulator or electrode, dislocation of the electrode with loss of efficacy, or loss of efficacy for no known reason (40, 41). However, this can often be corrected by reprogramming the stimulator, and up to 75 % of the patients will need this (42). Furthermore, 16 %–54 % of patients will need reoperation, to replace the electrode after technical failure or to move the stimulator because of local discomfort (19, 31, 40, 41). A total of 8 %–20 % of the patients will eventually have the equipment explanted because of technical failure, pain or discomfort (12, 19, 31, 43).

Follow-up

Since many of the patients will need reprogramming or reoperation, it is essential to have a good and readily available follow-up service (42). At the University Hospital of North Norway we have chosen to let the patient him/herself determine the need for follow-up. In addition, we have established an annual training course, including an offer for checking and possibly reprogramming the stimulator in connection with the course.

Conclusion

Sacral nerve stimulation can be an effective form of treatment of overactive bladder, non-obstructive urinary retention, faecal incontinence, constipation and chronic pain in the pelvic floor area. The treatment is minimally invasive, and the efficacy of the treatment can be determined by means of a brief test period. Most of those who have a stimulator implanted will retain the effect for a number of years. However, many patients will need reprogramming of the stimulator or reoperation to replace the electrode, and this necessitates close follow-up to maintain optimal efficacy.

Stig Norderval (b. 1961)
is Senior Consultant at the Department of Gastroenterological Surgery, and chairman of the steering committee of the Norwegian Continence and Pelvic Floor Centre. He has a PhD in sphincter lesions, incontinence and anal ultrasound. In 2010–2011 he was Visiting Scholar at the Colorectal Unit, St. Vincent's Hospital, Melbourne.
Stated conflicts of interest: Has received fees from Medtronic for lectures.

Mona Rydningen (b. 1973)
is an MD, has worked at the Surgical Department and is currently in specialisation at the Department of Gastroenterological Surgery.
Stated conflicts of interest: Has received travel allowances from Medtronic to attend courses arranged by the company.

Rolv-Ole Lindsetmo (b. 1959)
has a doctorate in medicine, a PhD degree and is a specialist in general surgery and gastroenterological surgery. He is head of the Department of Gastroenterological Surgery and professor of clinical medicine.
Stated conflicts of interest: None

Dag Lein (b. 1951)
is a specialist in urology, general surgery and breast and endocrine surgery.
Stated conflicts of interest: Has received travel allowances from Medtronic to attend courses arranged by the company.

Barthold Vonen (b. 1953)
is a specialist in general surgery and gastroenterological surgery, and Professor of Surgery at the Institute of Clinical Medicine. He is Deputy Chief Executive of Nordlandssykehuset Hospital in Bodø.
Stated conflicts of interest: Has received travel allowances from Medtronic to attend courses arranged by the company.

>>>

References

1. Brindley GS, Polkey CE, Rushton DN et al. Sacral anterior root stimulators for bladder control in paraplegia: the first 50 cases. J Neurol Neurosurg Psychiatry 1986; 49: 1104–14.
2. Tanagho EA, Schmidt RA, Orvis BR. Neural stimulation for control of voiding dysfunction: a preliminary report in 22 patients with serious neuropathic voiding disorders. J Urol 1989; 142: 340–5.
3. Matzel KE, Stadelmaier U, Hohenfellner M et al. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. Lancet 1995; 346: 1124–7.
4. Bazeed MA, Thüroff JW, Schmidt RA et al. Effect of chronic electrostimulation of the sacral roots on the striated urethral sphincter. J Urol 1982; 128: 1357–62.
5. Shaker HS, Hassouna M. Sacral root neuromodulation in idiopathic nonobstructive chronic urinary retention. J Urol 1998; 159: 1476–8.
6. Leng WW, Chancellor MB. How sacral nerve stimulation neuromodulation works. Urol Clin North Am 2005; 32: 11–8.
7. Malaguti S, Spinelli M, Giardiello G et al. Neurophysiological evidence may predict the outcome of sacral neuromodulation. J Urol 2003; 170: 2323–6.
8. Weil EH, Ruiz-Cerdá JL, Eerdmans PH et al. Clinical results of sacral neuromodulation for chronic voiding dysfunction using unilateral sacral foramen electrodes. World J Urol 1998; 16: 313–21.
9. Elkelini MS, Hassouna MM. Safety of MRI at 1.5Tesla in patients with implanted sacral nerve neurostimulator. Eur Urol 2006; 50: 311–6.
10. Uitti RJ, Tsuboi Y, Pooley RA et al. Magnetic resonance imaging and deep brain stimulation. Neurosurgery 2002; 51: 1423–8.
11. Faucheron JL, Voirin D, Badic B. Sacral nerve stimulation for fecal incontinence: causes of surgical revision from a series of 87 consecutive patients operated on in a single institution. Dis Colon Rectum 2010; 53: 1501–7.
12. van Voskuilen AC, Oerlemans DJ, Weil EH et al. Long term results of neuromodulation by sacral nerve stimulation for lower urinary tract symptoms: a retrospective single center study. Eur Urol 2006; 49: 366–72.
13. van Kerrebroeck PE, van Voskuilen AC, Heesakkers JP et al. Results of sacral neuromodulation therapy for urinary voiding dysfunction: outcomes of a prospective, worldwide clinical study. J Urol 2007; 178: 2029–34.
14. White WM, Dobmeyer-Dittrich C, Klein FA et al. Sacral nerve stimulation for treatment of refractory urinary retention: long-term efficacy and durability. Urology 2008; 71: 71–4.
15. Das AK, Carlson AM, Hull M. Improvement in depression and health-related quality of life after sacral nerve stimulation therapy for treatment of voiding dysfunction. Urology 2004; 64: 62–8.
16. Hunskår S. Behandling av overaktiv blære-syndrom. Tidsskr Nor Lægeforen 2005; 125: 2029–30.
17. Groenendijk PM, Lycklama à Nyeholt AA, Heesakkers JP et al. Urodynamic evaluation of sacral neuromodulation for urge urinary incontinence. BJU Int 2008; 101: 325–9.
18. Siddiqui NY, Wu JM, Amundsen CL. Efficacy and adverse events of sacral nerve stimulation for overactive bladder: A systematic review. Neurourol Urodyn 2010; 29 (suppl 1): S18–23.
19. Michelsen HB, Thompson-Fawcett M, Lundby L et al. Six years of experience with sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 2010; 53: 414–21.
20. Melenhorst J, Koch SM, Uludag O et al. Is a morphologically intact anal sphincter necessary for success with sacral nerve modulation in patients with faecal incontinence? Colorectal Dis 2008; 10: 257–62.
21. Maeda Y, Norton C, Lundby L et al. Predictors of the outcome of percutaneous nerve evaluation for faecal incontinence. Br J Surg 2010; 97: 1096–102.
22. Hollingshead JR, Dudding TC, Vaizey CJ. Sacral nerve stimulation for faecal incontinence: results from a single centre over a 10 year period. Colorectal Dis 2010; e-publisert 16.8.
23. Wexner SD, Coller JA, Devroede G et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. Ann Surg 2010; 251: 441–9.
24. Leroi AM, Parc Y, Lehur PA et al. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. Ann Surg 2005; 242: 662–9.
25. Vaizey CJ, Kamm MA, Roy AJ et al. Double-blind crossover study of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 2000; 43: 298–302.
26. Dudding TC, Meng Lee E, Faiz O et al. Economic evaluation of sacral nerve stimulation for faecal incontinence. Br J Surg 2008; 95: 1155–63.
27. Muñoz-Duyos A, Navarro-Luna A, Brosa M et al. Clinical and cost effectiveness of sacral nerve stimulation for faecal incontinence. Br J Surg 2008; 95: 1037–43.
28. Govaert B, Melenhorst J, Nieman FH et al. Factors associated with percutaneous nerve evaluation and permanent sacral nerve modulation outcome in patients with fecal incontinence. Dis Colon Rectum 2009; 52: 1688–94.
29. Varma JS, Binnie N, Smith AN et al. Differential effects of sacral anterior root stimulation on anal sphincter and colorectal motility in spinally injured man. Br J Surg 1986; 73: 478–82.
30. Kamm MA, Dudding TC, Melenhorst J et al. Sacral nerve stimulation for intractable constipation. Gut 2010; 59: 333–40.
31. Maeda Y, Lundby L, Buntzen S et al. Sacral nerve stimulation for constipation: suboptimal outcome and adverse events. Dis Colon Rectum 2010; 53: 995–9.
32. Holzer B, Rosen HR, Novi G et al. Sacral nerve stimulation in patients with severe constipation. Dis Colon Rectum 2008; 51: 524–9, discussion 529–30.
33. Kenefick NJ, Vaizey CJ, Cohen CR et al. Double-blind placebo-controlled crossover study of sacral nerve stimulation for idiopathic constipation. Br J Surg 2002; 89: 1570–1.
34. Kim JH, Hong JC, Kim MS et al. Sacral nerve stimulation for treatment of intractable pain associated with cauda equina syndrome. J Korean Neurosurg Soc 2010; 47: 473–6.
35. Dudding TC, Vaizey CJ, Jarrett ME et al. Permanent sacral nerve stimulation for treatment of functional anorectal pain: report of a case. Dis Colon Rectum 2007; 50: 1275–8.
36. Govaert B, Melenhorst J, van Kleef M et al. Sacral neuromodulation for the treatment of chronic functional anorectal pain: a single center experience. Pain Pract 2010; 10: 49–53.
37. Lundby L, Krogh K, Buntzen S et al. Temporary sacral nerve stimulation for treatment of irritable bowel syndrome: a pilot study. Dis Colon Rectum 2008; 51: 1074–8.
38. Sievert KD, Amend B, Gakis G et al. Early sacral neuromodulation prevents urinary incontinence after complete spinal cord injury. Ann Neurol 2010; 67: 74–84.
39. Wexner SD, Hull T, Edden Y et al. Infection rates in a large investigational trial of sacral nerve stimulation for fecal incontinence. J Gastrointest Surg 2010; 14: 1081–9.
40. Hijaz A, Vasavada SP, Daneshgari F et al. Complications and troubleshooting of two-stage sacral neuromodulation therapy: a single-institution experience. Urology 2006; 68: 533–7.
41. Datta SN, Chaliha C, Singh A et al. Sacral neurostimulation for urinary retention: 10-year experience from one UK centre. BJU Int 2008; 101: 192–6.
42. Govaert B, Rietveld MP, van Gemert WG, Baeten CG. The role of reprogramming in sacral nerve modulation for faecal incontinence. Colorectal Dis 2011; 1: 78–81.
43. Melenhorst J, Koch SM, Uludag O et al. Sacral neuromodulation in patients with faecal incontinence: results of the first 100 permanent implantations. Colorectal Dis 2007; 9: 725–30.

Received 14 December 2010, first revision submitted 7 April 2011, approved 14 April 2011. Medical editor: Are Brean.