Reprogramming Sacral Neuromodulation for Sub-Optimal Outcomes: Evidence and Recommendations for Clinical Practice

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ABSTRACT

Objectives: In some patients treated for urinary or fecal incontinence with sacral neuromodulation (SNM) persistence of symptoms, a reduction in efficacy or adverse effects of stimulation can occur. In such situations, further programming of the SNM device can help resolve problems. Infrequently hardware failure is detected. This article aims to provide practical guidance to solve sub-optimal outcomes (troubleshooting) occurring in the course of SNM therapy.

Materials and Methods: A systematic literature review was performed. Collective clinical experience from an expert multidisciplinary group was used to form opinion where evidence was lacking.

Results: Circumstances in which reprogramming is required are described. Actions to undertake include changes of electrode configuration, stimulation amplitude, pulse frequency, and pulse width. Guidance in case of loss of efficacy and adverse effects of stimulation, developed by a group of European experts, is presented. In addition, various hardware failure scenarios and their management are described.

Conclusions: Reprogramming aims to further improve patient symptoms or ensure a comfortable delivery of the therapy. Initial changes of electrode configuration and adjustment of stimulation parameters can be performed at home to avoid unnecessary hospital visits. A logical and stepwise approach to reprogramming can improve the outcome of therapy and restore patient satisfaction.

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INTRODUCTION

Sacral neuromodulation (SNM) is an established therapy to manage a variety of functional bladder and/or bowel disorders. Patient selection, optimal lead placement, and device programming are all important factors that can affect the outcome. Recent refinement of the surgical technique for lead placement has resulted in improved short- and mid-term treatment success (1,2). A practical algorithm for initial programming of SNM has also been reported ensuring immediate benefit of therapy for many patients following device implant (3).

In some patients undergoing SNM, symptoms may persist, or treatment efficacy may decline to an unsatisfactory level over time. In these circumstances, further programming can result in improvement of symptoms and higher patient satisfaction. Adverse events (AE) related to electrical stimulation can also occur and reprogramming may allow resolution of any unwanted effects of therapy (4).

With these situations in mind, our group has worked to elaborate practical solutions. This article aims to provide a guide to colleagues dealing with poor outcomes in SNM therapy. It covers common problems encountered in clinical practice and furthermore describes how to streamline SNM follow-up services to reduce the follow-up burden for health-care professionals and patients.

METHOD

Over the last 5 years, our European Interdisciplinary Expert Group (13 implanters, either urologists or colorectal surgeons, with a cumulative SNM experience of more than 264 years) has conducted a survey of SNM practice based on literature review and personal experience in the field of functional urological and bowel disorders. Studying all the steps of the therapy in depth has allowed us to develop thoughtful guidance with the aim to improve the understanding and outcomes of SNM therapy (1,3,5).

This fourth report addresses recommendations and interventional algorithms for reprogramming in those patients that have sub-optimal outcomes from SNM. Often termed "troubleshooting" it illustrates what to do in situations when symptoms persist, efficacy is lost, or adverse effects of stimulation occur. Other complications not directly related to electrical stimulation such as post-operative device infections are already covered by established guidelines (6) and thus were excluded from this work.

A systematic literature search was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement using Embase and Pubmed databases and the search strategy terms: [(sacral nerve stimulation) OR (sacral neuromodulation) AND (reprogramming)] (7). Some publications concerning SNM therapy contain information about reprogramming which is not evident in the keywording. Therefore electronic and hand-searching of key articles on SNM and cross-referencing was also performed. All full-text articles in the English language that contained information on either the methods of reprogramming, the success rates of reprogramming, or the frequency of reprogramming were included. The search cut-off date was December 31, 2020. Studies or reports containing a subject number of fewer than five patients, pediatric patients, or for indications other than overactive bladder, non-obstructive urinary retention, fecal incontinence, or chronic pelvic pain were excluded.

SNM REPROGRAMMING: WHY, WHEN, AND HOW?

Why Reprogram SNM Settings?

Reprogramming is wholly required in two circumstances: to deal with a poor outcome due to a loss of efficacy or AE of stimulation (4). It is most commonly performed during the first 3 to 12 months of therapy perhaps reflecting sub-optimal lead placement, neurological adaptation to the therapy, healing processes, or the pursuit of complete symptom resolution by patients and/or clinicians (6,8–11). Patients achieving a low amplitude response to stimulation during lead placement are less likely to require reprogramming (12) whilst multiple early changes in stimulation parameters may be a predictive factor for poor long-term outcome (13).

Reprogramming can involve changing the electrode configuration and/or parameters of stimulation with the objective of finding optimal settings which are individual to each patient. There is no current evidence to suggest that different parameters (pulse width, amplitude, and frequency) should be used initially for different clinical indications (e.g., urinary vs. bowel) (5). However, in some situations, altering the stimulation parameters has been shown to have an impact on the outcomes of the therapy (14–18).

There are multiple permutations in stimulation settings that may be confusing or intimidating to a health-care professional responsible for reprogramming the implantable pulse generator (IPG) for a given patient. The literature suggests that the majority of patients will have at least one program change (8,9,12,13,19–33) (Table 1). In most studies the rationale for further programming and whether this is patient or clinician initiated is unclear. The changes made to settings are rarely described however there is sufficient evidence in the literature that

Table 1. Reported Frequency of Required Reprogramming From Studies With at Least Five Patients.

First author/year	Indication	N (total)	Mean number of reprogramming (SD)	Mean follow-up (SD) in months [range]	Conditions (if stated)
Zhang 2019 (19)	OAB	22	1.53 (NR)[*]	17.30 (3.29) [12–22]	
Marinkovic 2018 (12)	OAB	174	1.13 (0.81)[†]	116.3 (30.3)	Motor response ≤3 V
Marinkovic 2018 (12)	OAB	110	1.86 (1.24)[†]	112.7 (34.6)	Motor response ≥4 V
Duelund-Jakobsen 2016 (20)	FI	186	2.8 (1.8)[*]	28.9 (18.4)	
Duelund-Jakobsen 2018 (9)	FI	40	2.0 (1.0)[*,†]	@12 months	3889 lead (curved stylet)
Duelund-Jakobsen 2018 (9)	FI	134	2.4 (1.2)[*,†]	@12 months	3093 lead (straight stylet)
Amundsen 2018 (21)	OAB	139	NR (only 10% of had ≥3 reprogramming[*])	@24 months	
Peters 2017 (13)	OAB/NOUR/CPP	273	1.8 (2.1)[*]	28.9 months follow-up [1.6–121.7][‡]	Non-reoperation group
Peters 2017 (13)	OAB/NOUR/CPP	134	3.8 (4.3)[*]	28.9 months follow-up [1.6–121.7][‡]	Reoperation group
Marinkovic 2015 (22)	OAB	62	1.4 (0.7)[†]	124.7 (21.5)[‡]	Only motor response during stage I
Marinkovic 2015 (22)	OAB	53	2.8 (1.1)[†]	120.4 (19.7)	Mixed sensory/motor response during stage I
Gilleran 2016 (23)	OAB/NOUR	171	1.7 (1.5)[*,†]	@12 months	4 active electrodes
Gilleran 2016 (23)	OAB/NOUR	48	1.8 (1.4)[*,†]	@12 months	3 active electrodes
Gilleran 2016 (23)	OAB/NOUR	25	2.1 (2.2)[*,†]	@12 months	1–2 active electrodes
Peters 2013 (24)	OAB/NOUR/CPP	63	1.9 (1.6)[*,†]	@12 months	Neurogenic LUTD
Peters 2013 (24)	OAB/NOUR/CPP	241	1.9 (1.8)[*,†]	@12 months	Non-neurogenic LUTD
Cameron 2013 (25)	OAB/NOUR/CPP	558	2.15[†]	In year 1	
Cameron 2013 (25)	OAB/NOUR/CPP	NR	0.70[†]	In year 2	
Cameron 2013 (25)	OAB/NOUR/CPP	NR	0.65[†]	In year 3	
Cameron 2013 (25)	OAB/NOUR/CPP	NR	0.48[†]	In year 4	
Cameron 2013 (25)	OAB/NOUR/CPP	NR	0.36[†]	In year 5	
Govaert 2011 (8)	FI	155	≈2.1[†]	@12 months	
Govaert 2011 (8)	FI	155	25.2% required no reprogramming at any follow-up visit	28.1 [1.0–93.6][‡]	
Cattle 2009 (26)	FI	38	2.68[*]	≤48 months	
Burks 2008 (27)	OAB/NOUR/CPP	47	≈2.0[†]	20 months	
Maxwell 2008 (28)	OAB	8	2.8 [0–5][*,†]	@12 months	
Maxwell 2008 (28)	CPP/IC	7	6.8 [2–16][*,†]	@12 months	
Maeda 2011 (29)	FI	176	2.25	11 [4–26][‡]	
Marinkovic 2010 (30)	NOUR	12	3.67 (2.22)[*]	52.2 (16.0)	Multiple sclerosis
Irwin 2017 (31)	FI	40	NR; reprogramming was required in 62.5% of cases	12 months	
Andretta 2014 (32)	OAB	7	0.9[*]	52 (26) months	Multiple sclerosis
Andretta 2014 (32)	Mixed (OAB + NOUR)	6	3.0[*]	52 (26) months	Multiple sclerosis
Marinkovic 2019 (33)	CPP/IC	100	1.0 (1.02)[†]	120.1 (33.3)	Motor response ≤3 V
Marinkovic 2019 (33)	CPP/IC	48	1.9 (0.9)[†]	116.3 (29.2)	Motor response >4 V

Note: The majority of papers in the published literature does not report on the details of programming changes and in those that do, often the effects of reprogramming on symptoms are unclear. In addition, historical data relating to non-tined lead implantation and prior to recent advances in operative standardized technique need to be interpreted with caution as they may not be relevant or reflect current practice.

[*]Total number of reprogramming sessions during the follow-up period.
[†]Annual number of reprogramming sessions.
[‡]Median follow-up.

CPP, chronic pelvic pain (bladder pain syndrome, interstitial cystitis); FI, fecal incontinence; IC, interstitial cystitis; LUTD, lower urinary tract dysfunction; NOUR, non-obstructive urinary retention; NR, not reported; OAB, overactive bladder; SD, standard deviation.

reprogramming can improve short-term outcome for patients experiencing poor results from SNM (14,15,19,26,28,29,34–45) (Table 2).

When to Reprogram SNM Settings?

The majority of patients do not have numerous attempts at reprogramming with only 17% (14/81) of patients requiring three or more attempts at reprogramming in one large randomized controlled trial (21). Reprogramming requirements appear to reduce over time. For example, in a cohort of 558 patients, a mean of 2.15 reprogramming sessions was reported in the first year of therapy, reducing to 0.7 in the second year and declining even further over subsequent years (25). The programming burden does not appear to be greater in patients who fail to obtain a

Table 2. Reported Success Rates of Reprogramming From Studies With at Least Five Patients With a Need for Reprogramming.

First author/year	Indication	N	Reason for reprogramming	Success rate of reprogramming, N (%)
Zhang 2019 (19)	OAB	17	Mixed	14/17 (82.4)
Blok 2019 (34)	OAB	11	Pain	11/11 (100)
Lenis 2013 (35)	OAB/NOUR	25	Mixed	4/25 (16.0)
Lenis 2013 (35)	OAB/NOUR	51	Loss of eff.	20/51 (39.2)
Lee 2013 (36)	OAB	19	Loss of eff.	11/19 (57.9)
Duelund-Jakobsen 2012 (15)	FI	11	Loss of eff.	8/11 (72.7)
Cattle 2009 (26)	FI	10	Loss of eff.	NR
Hetzer 2007 (37)	FI	6	Pain	5/6 (83.3)
van Voskuilen 2006 (38)	OAB/NOUR	16	Loss of eff.	11/16 (68.8)
McLennan 2003 (39)	OAB/IC	10	Loss of eff.	7/10 (70.0)
Maxwell 2008 (28)	OAB/IC/NOUR	17	Mixed	16/16 (100)
Noblett 2017 (40)	OAB	<53*	Pain	NR (≈75)
Dudding 2009 (14)	FI	12	Loss of eff.	8/12 (66.7)
Deng 2006 (41)	OAB/NOUR	5	Loss of eff.	2/5 (40)
Maeda 2011 (29)	FI	149*	Loss of eff.	79/299 (26.4)
Maeda 2011 (29)	FI	77*	Pain	59/77 (76.6)
Marcelissen 2011 (42)	OAB/NOUR	50	Loss of eff.	38/50 (76)
Benson 2020 (43)	OAB	7	Pain	7/7 (100)
Zhang 2019 (44)	OAB	9	Mixed	9/9 (100)
Sutherland 2007 (45)	OAB/NOUR	36	Loss of eff.	7/36 (19.4)
Sutherland 2007 (45)	OAB/NOUR	14*		NR (≈78)

*Number of reprogramming events.
FI, fecal incontinence; IC, interstitial cystitis; loss of eff., lack or loss of effectiveness, recurrent symptoms, loss of clinical response, maintenance of the therapy; mixed, pain and loss of effectiveness; N, total number of patients in need of reprogramming events; NOUR, non-obstructive urinary retention; NR, not reported; OAB, overactive bladder; pain, including adverse stimulation, undesirable change in stimulation, stimulation pain at the implant site.

sensory response in all four electrodes during initial (basic) programming (23) or in those with progressive neurological diseases (24).

Changes in SNM settings should not be performed for transient changes in outcome measures (i.e., increased fecal incontinence due to loose stools resulting from antibiotic use). It should only be considered if the patient is unsatisfied with the outcome of SNM therapy. As part of the consent process for treatment, realistic expectations regarding the potential benefits of SNM should be discussed. Outcomes from chronic stimulation may not be the same as those seen during the initial stages of therapy. The majority of patients will continue to have some symptoms however this does not equate to treatment failure (46,47). Reprogramming can often enhance or restore SNM efficacy. However, in some patients further improvement or complete resolution of symptoms is not achievable.

How to Reprogram SNM Settings
Electrode Configuration
Electrode configuration changes should be made using the principles of basic SNM programming with the aim to achieve midline sensation with low amplitude stimulation (3). If several configurations exist that produce midline sensation, efficacy may be improved by widening the stimulation field (further the distance between active bipolar electrodes or switch to monopolar stimulation). Likewise, adverse effects of stimulation may be reduced by narrowing the stimulation field (reduce the distance between active bipolar electrodes or switch to bipolar stimulation from a monopolar setting).

Up to one-third of patients may have an unreliable, unquantifiable sensory response which makes programming electrode configuration difficult (39). In these patients, anal electromyogram measurement has been used to guide programming. It can improve SNM outcomes, but this is not currently standard practice (14,36,39).

Impedance and Amplitude
Tissue encapsulation around an implanted tined lead can increase electrical impedance leading to reduced delivery of energy to the target nerve (48). A greater stimulation amplitude may be required to counteract this higher impedance (Ohms law). Increase of impedance (20–48%) has been observed in the first 3–6 months after implantation (49–51). In most patients, the small change in impedance observed is unlikely to affect the outcome of therapy. Stimulation amplitude can be set well below the habituated sensory threshold without compromising patient satisfaction or functional outcomes (18,52,53). There are some patients in whom treatment efficacy declines over time and an increase in stimulation amplitude may be required to restore therapeutic efficacy (54,55). Modern constant current neurostimulation systems may require less amplitude amendment as a dynamic voltage adjusts for changes in resistance within the circuit (49).

Pulse Frequency
Changing this stimulation parameter affects the recruitment of different nerve fiber types (56). Whilst a standard frequency of 14 Hz will elicit a response in the majority of patients (3), an alternative frequency may be required to obtain a clinical response or optimize efficacy in others (14,15,18,42,57,58). In a study of 50 urological patients, changing pulse frequency to a lower or higher setting (5.2, 10, 21, or 40 Hz) was not shown to be superior when analyzing group data (42). However, 76% of patients had an improvement in symptoms with a change of

frequency away from the standard setting. In 20% of patients suffering from overactive bladder, changing pulse frequency resulted in complete dryness and 22% of "urinary retention" patients stopped self-catheterization (42). In a randomized controlled trial including patients with FI and sustained loss of efficacy a trend was found towards higher patient satisfaction and improved clinical outcome at 3 months with high-frequency stimulation (31 Hz). This was preferred by more than half of the patients (15). Similarly, in a series of 12 patients with partially improved FI following SNM, 6 patients experienced a clinical improvement with high-frequency stimulation (14).

An explanation may be found in a study that measured somatosensory evoked potentials of the pudendal nerve in patients with urological dysfunctions. The authors demonstrated that high-frequency stimulation (40 Hz) more effectively reinforces afferent signal transmission to the central nervous system than lower frequencies (21 Hz) (59). Even higher frequencies have been described for SNM in the treatment of chronic pelvic pain with a similar conclusion although it seems difficult to find a single frequency that works best for every patient in this population (60).

Reprogramming Pulse Width

In pre-clinical studies, no dependency on pulse width has been demonstrated (5). However, like pulse frequency, changing this stimulation parameter can also affect nerve recruitment (61) and changing from the standard setting (210 μsec) may improve or worsen symptoms in some patients (14,15,17). Low pulse width stimulation reduces the recruitment of smaller diameter nerve fibers with afferent Aδ and C fibers requiring a longer duration of stimulation to produce an excitatory response (4,61). Reducing the pulse width in patients experiencing painful stimulation can reduce adverse symptoms but may also reduce treatment efficacy. Conversely, increasing the pulse width may elicit pain. Pulse width up to 330 μsec has been utilized in patients with underlying neurologic diseases, such as cauda equina syndrome, as their sensory perception is often compromised (62).

GUIDANCE FOR PROBLEM-SOLVING IN SNM TROUBLESHOOTING

Problem-Solving When Facing a SNM Loss of Efficacy

In patients that fail therapy during the first year of SNM, or when a lack of efficacy is observed immediately after implantation, often no firm explanation for deterioration can be identified (63,64). Poor patient selection or suboptimal implantation technique may be found to be a factor (65) and in these individuals, reprogramming is unlikely to be successful. Patient compliance with therapy should also be considered, especially in those who have a rechargeable device. In those not receiving continuous delivery of SNM the maximum benefits of therapy may not be seen.

After initial basic programming has been performed (3), patients still experiencing significant symptoms can be considered for further reprogramming. Any factors that could account for a change of efficacy should be explored. These include a history of trauma and the introduction of a new diet or medication. A sudden loss of efficacy, new adverse symptoms, a significant change in the site of sensation, or a complete absence of sensation on increasing stimulation amplitude, may be related to device failure or major lead migration (4).

Patient perception of gradually worsening symptoms can be difficult to quantify but needs to be considered. Some patients that subjectively report a loss in efficacy are found objectively to have had no deterioration when symptoms are re-evaluated. A "Honeymoon" period may exist where the patient is initially delighted with the therapy, but the improvement initially seen is forgotten over time. Behavioral changes, aging, and further deterioration of the underlying patient's condition may also cause worsening of symptoms.

In Practice

Initial troubleshooting can be performed at home using the patient's own programmer. By using telephone or video-conferencing technology, many aspects of programming can be performed without the need for face-to-face patient interaction, especially for those in whom multiple settings have been set on the patient programmer (66). Patients that are unfamiliar with the use of their programmer may need careful step-by-step instruction in order to change settings correctly.

Occasionally, the patient is found to have their IPG switched "OFF." In this situation, the implant should be simply switched back "ON" with no change made to the electrode configuration or stimulation parameters. Follow-up should be arranged to ascertain if effectiveness has been restored.

In patients in whom it is confirmed that the IPG is "ON," initial management should be to increase the amplitude of stimulation to the sensory threshold (Fig. 1). This value and the location of stimulation sensation are recorded. If sensation cannot be felt even at high amplitudes, this may indicate component failure or lead dislocation.

In patients in whom an increase in amplitude has not been successful in improving efficacy, and in whom additional programs have not been set, further review in the clinic is indicated (Fig. 1):

- An impedance check is initially performed to test the integrity of the system.
- The stimulation site and sensory threshold of the existing settings should be assessed.
- If midline sensation cannot be elicited at low amplitude stimulation then the optimum electrode configuration should be re-defined using basic programming principles (3). In the experience of the expert group, if two electrode configurations have demonstrated midline sensation at low amplitude stimulation, testing further configurations is unlikely to yield any improvement in outcome. There is no evidence that using double (extended) cathode array or reversing the polarity of stimulation provides a superior result.
- If a satisfactory response to low amplitude stimulation is found, one of these strategies can be tried.
  1. The second preferred electrode setting that achieves midline sensation can be tried (termed the "next best" electrode configuration). This is ascertained by the basic programming algorithm.
  2. Switching from monopolar to bipolar stimulation or vice versa may elicit a different response in some patients due to changes in the shape and penetration of the electrical field (26,27,67).
  3. Altering pulse frequency can be tried as previously described (14,15,18,42,68).

Only one change in setting should be performed at a time to allow proper evaluation of the adjustment. However, to prevent
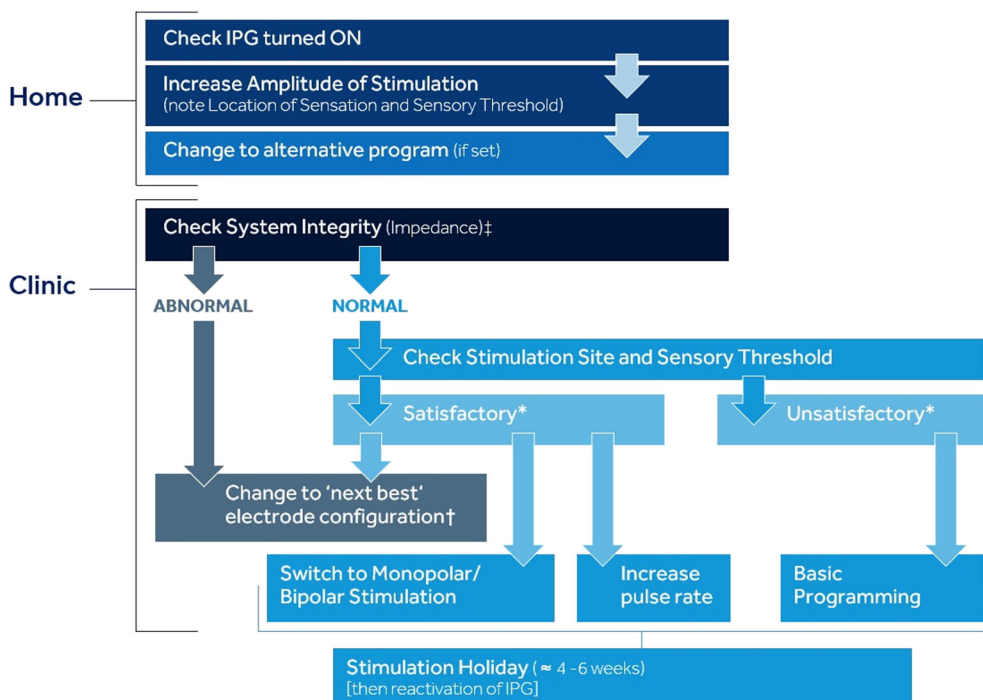
Figure 1. Sacral neuromodulation reprogramming algorithm in case of loss of efficacy.
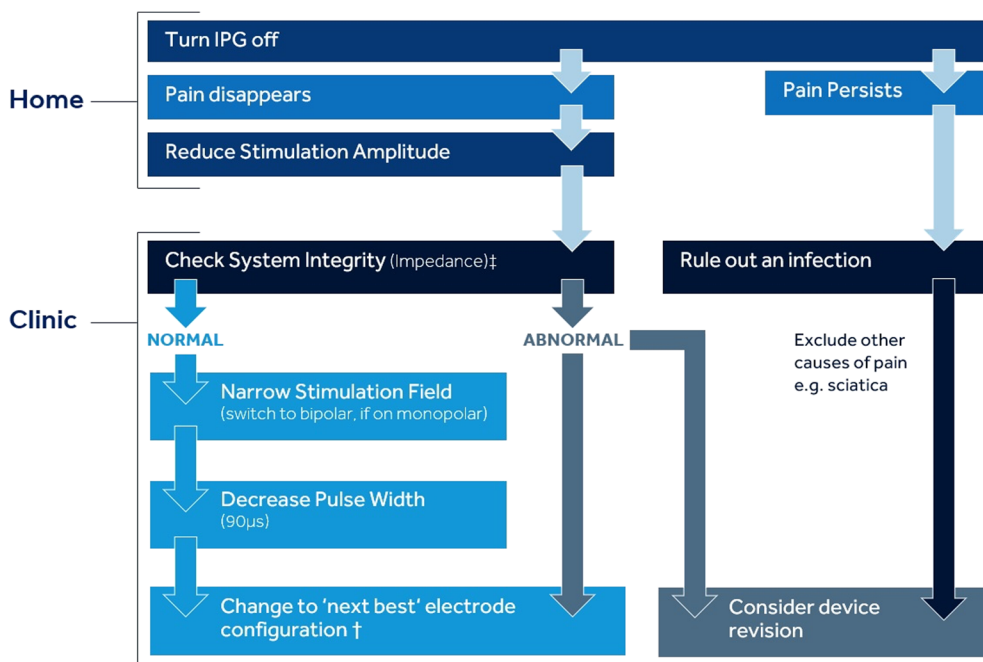

Figure 2. Sacral neuromodulation reprogramming algorithm in case of adverse effects of stimulation.

repetitive trips to the clinic, the patient's programmer can be set up with all three strategies to enable the patient to try each setting remotely. Patients should be instructed to try each program for at least 3 weeks before changing settings as natural fluctuations of symptoms and placebo effects occurring due to clinician–patient interactions, may confound outcome measures (69).

If efficacy remains poor after implementing the above strategy, a final option used by clinicians is the so-called "stimulation holiday" in which the device is turned off for several weeks (70). This allows the patient to return to their baseline symptoms, possibly with a change in nerve plasticity. The benefits of therapy, if restored, are appreciated when the implant is switched back on.

Lead migration is often cited as a cause for therapy failure although the true incidence is likely to be around 2% with the current lead design (41). Radiologically, migration is difficult to appreciate due to differences in angulation and projection between serial

x-rays. Small movements of the lead are unlikely to result in efficacy loss that cannot be rectified with re-programming. In those in whom midline sensation at low amplitude stimulation cannot be obtained, (as a result of poor initial lead placement, lead migration, or component failure) revision surgery can be considered regardless of x-ray appearance. Imaging may be useful however to illustrate the cause of treatment failure to a patient in some cases.

Problem-Solving When Facing Adverse Effects of Stimulation

Common AE related to electrical stimulation include pain, discomfort (often affecting the buttock or leg), transient electric shocks, unwanted vaginal or penile sensation, and unintentional changes in voiding or defecation. Reported predictors of AE include a history of trauma, change in body mass index, anxiety, patient age under 55, enrollment in a pain clinic, and a history of other AE (71–73).

In Practice

The approach to manage AE related to stimulation is similar to that of managing loss of efficacy. Initial management can be performed remotely. A thorough history of the undesirable symptoms experienced should be obtained. Symptoms of irregular, jolting "electrical" shocks may indicate a system short-circuit.

Patients experiencing pain should be asked to initially turn off the device to see if the symptoms resolve (Fig. 2).

- If symptoms persist the pain is likely related to local complications such as infection or the physical presence of the device itself, or secondary to unrelated causes such as back pain or sciatica.

- In those who have adverse symptoms from stimulation, switching "OFF" the device should rapidly result in complete relief. In those with intermittent symptoms (e.g., occasional sensation of electrical shock) a period of observation over several weeks may be required.
- In those patients in whom switching the device off resolves symptoms the initial management should be to decrease the amplitude of stimulation by up to 50% of the habituated sensory threshold. If this fails to resolve the symptoms, or the efficacy of SNM is reduced, then further programming will be required in the clinic.
- If a patient returns to the clinic, prior to any program changes an impedance check should be performed to check system integrity. If no damage to the system is observed similar steps to those for patients with loss of efficacy should be implemented but with the additional option of decreasing the pulse width (Fig. 2).

HARDWARE (DEVICE) FAILURE

Hardware-related complications, frequently preceded by trauma following falls, include device malfunction (either IPG or lead) and lead breakages due to microfractures with resultant abnormal impedances (71). Reported rates of device failure appear to have reduced over time (35,40,63,74,75). This is likely due to improvements in device technology with smaller implants and reduced number of components. In a large single-center study with 407 implanted patients, device malfunction and lead failure rates of 4.4% and 2.7% have been observed respectively (13).

Transient electrical shocks or jolts typical for intermittent short circuits (<50 Ω) have been reported in 5.5% of patients in early

Table 3. Revision Rates of SNM Reported Between 2015 and 2020 in Studies of Greater Than 50 Patients.

Author/year	Indication	N (total)	Revision rate (%)	Follow-up (months)
Gorissen 2015 (83)	FI	61	1.6	13
Johnson 2015 (84)	FI	145	4.1	12
Singh 2015 (85)	OAB	65	1.5	6
Duelund-Jakobsen 2016 (86)	FI	164	15.2	22
Siegel 2016 (87)	OAB	272	<20	36
Faris 2017 (77)	OAB, NOUR	315	24.1	n/a
Janssen 2017 (75)	FI	325	34.5	85.2
Kavvadias 2017 (88)	OAB, NOUR, PBS, FI	59	25.4	16.5
Noblett 2017 (40)	OAB	272	9	12
Amundsen 2018 (21)	OAB	139	3	24
Pizzaro-Berchidevsky 2018 (89)	OAB (NOUR, FI)	176	19.3	10.5
Banakhar 2019 (90)	OAB, NOUR	63	6.3	24
Gevelinger 2020 (73)	FI, LUTS	219	4.5	n/a
Greenberg 2019 (91)	OAB	225	9.8	44.7
Kirss 2019 (74)	FI	313	4.4	28.8
Oliveira 2019 (92)	FI	129	<11	36.7
Widmann 2019 (93)	FI, Const	79	30.4	52.8
Zhang 2019 (94)	OAB, IC/PBS, NOUR, FI	247	3.2	20.1
Benson 2020 (43)	OAB	129	1.6	12
De Meyere 2020 (95)	FI (incl. LARS)	62	14.5	30
Feldkamp 2021 (96)	OAB (NOUR, NB, FI, Const)	118	<10	13.6
Kaaki 2020 (97)	OAB	55	9.1	32
Morgan 2020 (98)	OAB (NOUR, FI)	183	23	52.8
Schönburg 2020 (99)	OAB, NOUR	56	12.5	50.2
Varghese 2020 (100)	FI	126	16.7	41.2

(): Low numbers of patients with indications mentioned within parentheses.
Const, constipation; FI, fecal incontinence; IC/PBS, interstitial cystitis, bladder pain syndrome; LARS, low anterior resection syndrome; LUTS, lower urinary tract symptoms; NB, neurogenic bladder; NOUR, non-obstructive urinary retention; OAB, overactive bladder.

SNM studies (76). This type of AE seems to have become rare, since it is not reported in more recent studies. Fracture of the insulation surrounding the lead extension cable used with Medtronic InterStim I (Medtronic, Minneapolis, MN, USA) devices may have accounted for this, being observed frequently during surgical revision of these early devices (expert opinion).

In Practice

In the advent of abnormal impedance check two situations exist:

- In the case of an *open circuit* (>4000 Ω), changing to an alternative electrode configuration may allow restoration of efficacy without the need for revision surgery. Obviously, if all four electrodes have failed, a lead replacement is required.
- If a *short circuit* (<50 Ω) is found, it is unlikely that further programming will be successful and revision surgery would appear to be inevitable (35).

SURGICAL REVISION AFTER SNM IMPLANTATION—SOME RECOMMENDATIONS

SNM revision surgery can be defined as any manipulation, relocation, or replacement of components performed in the operating room (excluding device explant) (77). At some point, due to the finite battery life of the IPG, almost all patients undergoing chronic SNM will require device revision. Therefore, it is argued that routine battery replacement should not be classed as a revision (22) and that there should be a distinction between anticipated and unplanned surgeries (78). In comparison to other treatments for pelvic floor disorders, such as the use of botulinum toxin, repeat injections are not seen as a treatment failure but part of a treatment cycle (79,80).

In the literature, rates for revision due to loss of efficacy or AE vary greatly, from 3% to 35%, even in recent large prospective studies (21,40,43,73–75,77,81–100) (Table 3). These differences depend on the length of follow-up, the devices used (smaller IPG, tined lead type, evolution of implantation techniques), the extent of thoughtful reprogramming (13), and the clinician or patient's willingness to proceed with further surgical intervention in an attempt to optimize outcome (77). In case of therapy failure, some patients may opt for device removal whilst others may wish only for deactivation. Patient selection is probably also a factor. A small number of patients can account for a large number of re-operations as illustrated in one cohort study of 202 patients, in which 38 (19%) of subjects accounted for 75% of all required revisions (71).

In Practice

In patients undergoing revision surgery, the pocket containing the IPG should be opened, and the device disconnected from the lead. The lead then should be tested, and the responses recorded.

1. In the case of low amplitude desirable responses (midline sensation and/or anal bellows ± plantar flexion of the hallux or forefoot), there is a risk that placement of a further lead may not benefit the patient. Some clinicians will implant a new tined or temporary stimulation lead at an alternative site that produces a satisfactory response. This is either connected to the existing IPG or brought out percutaneously and connected to an external neurostimulator for evaluation.
2. The lead should be removed if sub-optimal or absent responses are experienced or there is known damage or significant migration of the lead. This is best performed by determining the site of previous lead entry (observing the scar) and mobilizing the lead at this point by local dissection and upwards traction. Trying to remove the lead directly from the IPG pocket should be avoided as it can result in lead breakage.
3. Once the lead has been removed a standard implant technique is used to implant a new lead (1).
4. The previously used foramen may not be suitable due to fibrosis of the tissues within this foramen. This can alter the response to electrical stimulation and may make lead placement difficult.
5. If a lead is placed on a contralateral side to the IPG pocket then the lead is usually run over the midline to the IPG rather than re-siting the existing implant.

CONCLUSIONS

We have previously shown that programming, a key step of SNM therapy, does not need to be complicated (3). Reprogramming may not be required in all patients however, in those in whom satisfactory outcomes are not obtained, a further change in settings can improve efficacy and reduce adverse symptoms. To avoid unnecessary hospital visits SNM service provision, including reprogramming and troubleshooting, can be enhanced with remote consultations via phone calls or video technology. With parameter changes pre-programmed by the physician, the patient has the ability to change multiple settings at home in addition to amplitude changes. It may not be possible for some technophobic or elderly patients who cannot or do not dare to use their programmer. Relatives or local health-care professionals may be able to help in the community. Future technology may allow remote monitoring and programming of devices via the internet with synchronized audio-visual communication allowing the physician to gain feedback from the patient (19).

Authorship Statement

Drs. Thomas C. Dudding and Paul A. Lehur designed the study. All authors contributed to the content of the manuscript. Drs. Paul A. Lehur and Thomas C. Dudding drafted the manuscript. All authors commented and then approved the final version of the manuscript.

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COMMENT

Many physicians struggle with post implantation reprogramming. Sometimes programming a patient's sacral neuromodulation (SNM) device can feel like a "black box" of infinite possibilities. In my years of teaching and training physicians, APPs and nursing staff on SNM, the most frequent questions center around programming the device to obtain optimal and consistent symptom improvement.

It often seems providers are seeking a secret formula: a perfect program or combination of electrodes that will bring the patient satisfying relief of their symptoms. Developing a robust neuromodulation program for your patients requires the ability to identify a patient appropriate for SNM, the surgical skills for optimal lead placement AND a post implantation management algorithm. The reason providers are seeking guidance or an algorithm for post implant care is the frustration that can come when the device expectations do not meet the patient's expectations. The authors mention the importance of setting realistic expectations with the patient regarding the potential benefit of SNM.

Setting realistic expectations is key to a robust SNM program. This involves consistent messaging and defining patient and provider roles before SNM and at subsequent post implant visits. Consistent messaging among you and your staff when educating patients about their chronic condition (Overactive Bladder (OAB), Fecal Incontinence (FI), Nonobstructive Urinary Retention), about SNM and about the patient/provider roles is essential. We need to understand the patient's treatment goal for their condition in addition to their voiding, bowel and fluid habits as these will impact the long-term success of any treatment; SNM notwithstanding. The expectation of the patient as an active participant in their treatment plan involves eliciting the patient's voiding, bowel and fluid habits and any

changes in their health at each post implant visit, before making any changes to the device. The provider's role in optimizing success is to establish realistic expectations regarding potential benefits of SNM therapy. The patient needs to understand that their chronic condition will not be cured, that there will be transient changes in symptoms and that the patient's voiding/bowel/fluid habits will continue to impact the long-term success. For example, if a patient drinks 2 Liters of soda this will negatively impact their symptoms before and after implantation.

Starting each post implant visit reviewing patient habits, changes in patient's health and comparison of pre and post implant symptoms helps to identify gaps in patient understanding or patient participation in their condition and treatment success. Changes in patient condition or habits should be addressed before changing a program. A program change is warranted when symptoms are no longer >50% improved, the patient is continuing their healthy bladder and bowel habits as prescribed before and during SNM trial, and treatment of other medical conditions that impact the success of SNM have been optimized.

The authors have laid out a systematic way of approaching the mechanical aspects of re-programming. They review the key components of SNM settings as well as how and when to change these settings to optimize the patient outcomes. They also lay out steps for approaching the most common patient complaints: loss of efficacy, unwanted stimulation and device failure.

When the groundwork has been laid, realistic expectations set and patient/provider roles defined, the authors have provided us with an excellent guide for troubleshooting the SNM device and optimizing success.

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