GMCA GREATER MANCHESTER COMBINED AUTHORITY

NHS in Greater Manchester

Greater Manchester EUR Policy Statement on:

Sacroneuromodulation for Urinary Retention and Constipation

GM Ref: GM029 & GM064

Version: 3.1 (28 January 2019)

Commissioning Statement

Sacroneuromodulation for Urinary Retention and Constipation	
Policy Exclusions **(Alternative commissioning arrangements apply)**	Sacroneuromodulation for urinary and faecal incontinence is not covered by this policy as it is currently commissioned by NHS England. Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).
Policy Inclusion Criteria	**NOTE:** There are a number of variations of the terminology, including sacral neuromodulation and sacral nerve stimulation. All variations relating to either urinary retention or to constipation are covered by this policy. Funding will be available on an individual patient basis for those patients who meet NICE IPG536 who: • have a confirmed diagnosis of Fowler's Syndrome (diagnosis should be confirmed by EMG) **OR** • have intractable non-obstructive urinary retention **Funding Mechanism** Individual prior approval provided the patient meets the above criteria. Requests must be submitted with all relevant supporting evidence. Clinicians can submit an individual funding request outside of this guidance if they feel there is a good case for clinical exceptionality. Requests must be submitted with all relevant supporting evidence.
Clinical Exceptionality	Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality. Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is: • Significantly different to the general population of patients with the condition in question. ***and as a result of that difference*** • They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.
Best Practice Guidelines	All providers are expected to follow best practice guidelines (where available) in the management of these conditions.

Contents

Policy Statement

Greater Manchester Health and Care Commissioning (GMHCC) Effective Use of Resources (EUR) Policy Team, in conjunction with the GM EUR Steering Group, have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMHCC/GM EUR Steering Group have reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

Equality & Equity Statement

GMHCC/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMHCC/CCGs are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMHCC/CCGs will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMHCC EUR Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMHCC evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact policyfeedback.gmscu@nhs.net.

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Joint Commissioning Board (GMJCB) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the GM EUR Operational Policy.

Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

Rationale behind the policy statement

Sacroneuromodulation is an established therapy for urinary and faecal incontinence. Its range of uses is expanding most notably into the treatment of urinary retention and constipation. These developments mean that its use needs to be managed to ensure it is applied in the most cost effective way possible and accessed by those patients who will gain the most benefit from it.

Treatment / Procedure

Sacral nerve stimulation involves applying an electric current to one of the sacral nerves via an electrode placed through the corresponding sacral foramen. The electrode leads are attached to an implantable pulse generator, which stimulates nerves associated with the lower urinary tract or bowel

Sacroneuromodulation is currently used to treat urge incontinence of the bladder, urinary retention, constipation and faecal incontinence.

Sacroneuromodulation is an established therapy for urinary and faecal incontinence. Its range of uses is expanding most notably into the treatment of urinary retention and constipation. These developments mean that its use needs to be managed to ensure it is applied in the most cost effective way possible and accessed by those patients who will gain the most benefit from it.

NOTE: Sacroneuromodulation treatment for the management of urinary and faecal incontinence is currently commissioned by NHS England.

Epidemiology and Need

Chronic urinary retention is frequently asymptomatic - a patient is able to urinate, but may experience lower urinary tract symptoms (LUTS), related to storage and voiding difficulties. This is in contrast to acute urinary retention, a medical emergency, which is painful and the patient is unable to urinate despite a full bladder. Chronic urinary retention, whilst not immediately life-threatening, can lead to hydronephrosis and renal impairment and puts the patient at risk of acute-on-chronic retention, so requires diagnosis and treatment.

Constipation is a common problem. It means either going to the toilet less often than usual to empty the bowels, or passing hard or painful faeces (stools or motions). Constipation may be caused by not eating enough fibre, or not drinking enough fluids. It can also be a side-effect of certain medicines, or related to an underlying medical condition. In many cases, the cause is not clear. First line treatment if not managed by diet is the use of laxatives. Ideally, laxatives should only be used for short periods of time until symptoms ease.

Adherence to NICE Guidance

There is no NICE Clinical Guidance available.

Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

Date of Review

Five years from the date of the last review, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

Glossary

Term	Meaning
Acute-on-chronic retention	Chronic urinary retention – the individual can urinate but has storage and voiding difficulties. Acute urinary retention is a medical emergency, which is painful and the patient is unable to urinate despite a full bladder. Acute-on-chronic retention occurs when an individual with chronic retention becomes suddenly unable to urinate.
Fowler's Syndrome	Fowler's Syndrome was first described by Professor Clare J Fowler in 1985 and consists of difficulty in passing urine and urinary retention due to the bladder's sphincter muscle's failure to relax. Fowler's affects young women in their twenties and thirties who infrequently pass urine with an intermittent stream. The sensation of urinary urgency which would normally be present with a full bladder is absent although when the bladder is full to capacity, pain and discomfort may be experienced and up to half the patients affected have polycystic ovaries. The patient may present to A&E unable to pass urine normally and the bladder is then drained via a catheter
Hydronephrosis	Distention of the renal calyces and pelvis with urine as a result of obstruction of the outflow of urine distal to the renal pelvis. Renal calyces - chambers of the kidney through which urine passes. Renal pelvis - a small funnel-shaped cavity of the kidney into which urine is discharged before passing into the ureter.
Renal impairment	The Kidneys are diseased or damaged in some way and do not function fully – the may affect some functions of the kidney, if all the functions are affected then the disease has progressed to renal failure

References

1. GM EUR Operational Policy

Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	17/09/2014
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	15/12/2014
Greater Manchester Association Governing Group	06/01/2015

Bolton Clinical Commissioning Group	27/03/2015
Bury Clinical Commissioning Group	04/03/2015
Heywood, Middleton & Rochdale Clinical Commissioning Group	20/03/2015
Manchester Clinical Commissioning Group	North: 13/01/2015 Central: 05/03/2015 South: 11/03/2015
Oldham Clinical Commissioning Group	06/01/2015
Salford Clinical Commissioning Group	06/01/2015
Stockport Clinical Commissioning Group	25/02/2015
Tameside & Glossop Clinical Commissioning Group	22/04/2015
Trafford Clinical Commissioning Group	17/03/2015
Wigan Borough Clinical Commissioning Group	04/03/2015

Appendix 1 – Evidence Review

Sacroneuromodulation for Urinary Retention and Constipation
GM029 & GM064

Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

Database	Result
NICE	CG171 The management of urinary incontinence in women (NHS England remit so not cited)
	IPG99 Sacral nerve stimulation for faecal incontinence (NHS England remit so not cited)
	IPG64 Sacral nerve stimulation for urge incontinence and urgency-frequency incontinence (NHS England remit so not cited)
	IPG536: Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention (Published 25/11/15) (Added at review: Jan 2016)
NHS Evidence and NICE CKS	NICE CKS Constipation (does not mention SNM so not cited below)
	NICE CKS Irritable Bowel Syndrome (does not mention SNM so not cited below)
	NICE CG61 Irritable bowel syndrome in adults (does not mention SNM so not cited below)
SIGN	SIGN 79 management of urinary incontinence in primary care (NHS England remit – not cited)
Cochrane	Sacral nerve stimulation for faecal incontinence and constipation in adults, Mowatt G, Glazener CMA, Jarrett M, Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD004464. DOI: 10.1002/14651858.CD004464.pub2, Last updated May 23, 2007
	Sacral nerve stimulation for faecal incontinence and constipation in adults, Thaha MA et al The Cochrane Library 2015, Issue 8, (Added at review: Jan 2016)
York	For constipation - Nil found (other papers on both constipation and IBS available)
BMJ Clinical Evidence	For constipation - Nil found (other papers on both constipation and IBS available)
BMJ Best Practice	For constipation - Nil found (other papers on both constipation and IBS available)
General Search (Google) - PubMed papers	Sacral neuromodulation therapy: a promising treatment for adolescents with refractory functional constipation, van Wunnik BP, Peeters B, Govaert B,

	Nieman FH, Benninga MA, Baeten CG., Dis Colon Rectum. 2012 Mar;55(3):278-85. doi: 10.1097/DCR.0b013e3182405c61.
	Sacral neuromodulation for the management of severe constipation: development of a constipation treatment protocol, Sharma A, Liu B, Waudby P, Duthie GS., Int J Colorectal Dis. 2011 Dec;26(12):1583-7. doi: 10.1007/s00384-011-1257-x. Epub 2011 Jun 30.
	Status of sacral neuromodulation for refractory constipation, C. G. M. I. Baeten, Volume 13, Issue Supplement s2, pages 19–22, March 2011
Medline / Open Athens - For 'retention'	Not done for 'urge' or 'faecal incontinence' as this is the remit of NHS England.
	Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation, Jonas U, Fowler CJ, Chancellor MB, Elhilali MM, Fall M, Gajewski JB, Grünewald V, Hassouna MM, Hombergh U, Janknegt R, van Kerrebroeck PE, Lylcklama a Nijeholt AA, Siegel SW, Schmidt RA., J Urol. 2001 Jan;165(1):15-9.
	Current Urology reports: Sacral nerve stimulation to treat nonobstructive urinary retention in women, Craig V. Comiter, September 2008 Volume 9, Issue 5 pp 405-411
	Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention, Siegel SW, Catanzaro F, Dijkema HE, Elhilali MM, Fowler CJ, Gajewski JB, Hassouna MM, Janknegt RA, Jonas U, van Kerrebroeck PE, Lycklama a Nijeholt AA, Oleson KA, Schmidt RA. Urology. 2000 Dec 4;56(6 Suppl 1):87-91.
	Sacral nerve stimulation for treatment of refractory urinary retention: long-term efficacy and durability, White WM, Dobmeyer-Dittrich C, Klein FA, Wallace LS., Urology. 2008 Jan;71(1):71-4. doi: 10.1016/j.urology.2007.08.034., Source: Department of Urology, University of Tennessee Medical Center, Knoxville, Knoxville, Tennessee 37920, USA. wwhite@mc.utmck.edu
Medline / Open Athens - For 'constipation' (Search for Cochrane cited author):	Sacral nerve neuromodulation for the treatment of lower bowel motility disorders, Kenefick NJ, Ann R Coll Surg Engl. 2006 Nov;88(7):617-23.
	Permanent sacral nerve stimulation for treatment of idiopathic constipation, Kenefick NJ, Nicholls RJ, Cohen RG, Kamm MA., Br J Surg. 2002 Jul;89(7):882-8.

Summary of the evidence

Sacroneuromodulation appears to be a safe and effective treatment for intractable urinary retention where standard medication has failed and the only alternative is regular self-catheterisation or the use of an indwelling catheter.

Sacroneuromodulation for constipation: The evidence of the effectiveness of this intervention is limited as the use of Sacroneuromodulation in the treatment of idiopathic constipation is still relatively new. The evidence available shows promising results for all ages studied although the treatment is still developmental. Most studies relate to idiopathic constipation or functional constipation. A percutaneous nerve evaluation (PNE) test in advance of offering the treatment is thought to be a good predictor of post implant treatment success although the evidence for this is limited.

The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

1. LEVEL 2: A PROSPECTIVE, RANDOMIZED MULTI-CENTRE MULTINATIONAL TRIAL

Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation., Jonas U, Fowler CJ, Chancellor MB, Elhilali MM, Fall M, Gajewski JB, Grünewald V, Hassouna MM, Hombergh U, Janknegt R, van Kerrebroeck PE, Lylcklama a Nijeholt AA, Siegel SW, Schmidt RA., J Urol. 2001 Jan;165(1):15-9.

Materials and Method: A total of 177 patients with urinary retention refractory to standard therapy were enrolled in the study. Greater than 50% improvement in baseline voiding symptoms during a 3 to 7-day percutaneous test stimulation qualified a patient for surgical implantation of an InterStim® system. Of the patients who qualified for implantation 37 were randomly assigned to a treatment and 31 to a control group. Patients in the treatment group underwent early surgical implantation of the sacral nerve stimulation system, while implantation was delayed in the control group for 6 months. Followup evaluations, including voiding diary analysis and temporary deactivation of the stimulator at 6 months, were conducted at 1, 3, 6, 12 and 18 months after implantation in the treatment group, and after 3 and 6 months in the control group.

Results: Compared to the control group, patients implanted with the InterStim system had statistically and clinically significant reductions in the catheter volume per catheterization ($p < 0.0001$). Of the patients treated with implants 69% eliminated catheterization at 6 months and an additional 14% had a 50% or greater reduction in catheter volume per catheterization. Therefore, successful results were achieved in 83% of the implant group with retention compared to 9% of the control group at 6 months. Temporary inactivation of sacral nerve stimulation therapy resulted in a significant increase in residual volumes ($p < 0.0001$) but effectiveness of sacral nerve stimulation was sustained through 18 months after implant.

Conclusions: Results of this prospective, randomized clinical study demonstrate that sacral nerve stimulation is effective for restoring voiding in patients with retention who are refractory to other forms of treatment.

2. LEVEL 2: A PROSPECTIVE, RANDOMIZED MULTI-CENTRE MULTINATIONAL TRIAL

Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention, Siegel SW, Catanzaro F, Dijkema HE, Elhilali MM, Fowler CJ, Gajewski JB, Hassouna MM, Janknegt RA, Jonas U, van Kerrebroeck PE, Lycklama a Nijeholt AA, Oleson KA, Schmidt RA., Urology. 2000 Dec 4;56(6 Suppl 1):87-91.

Abstract

Many patients have chronic, debilitating symptoms of voiding dysfunction that are refractory to conventional medical or surgical therapies. This multicenter, prospective study evaluated the long-term effectiveness of sacral nerve stimulation using the implantable Medtronic InterStim therapy for urinary control in patients with otherwise intractable complaints of urinary urge incontinence, urgency-frequency, or retention. Each patient first underwent temporary, percutaneous sacral nerve test stimulation. If at least a 50% reduction in target symptoms was documented for at least 3 days, patients received a permanent Medtronic InterStim sacral nerve stimulation system that includes a surgically implanted lead

and neurostimulator. Regular follow-up was conducted with outcome data. We report here on patients who have been observed from 1.5 to 3 years postimplantation. The results demonstrate that after 3 years, 59% of 41 urinary urge incontinent patients showed greater than 50% reduction in leaking episodes per day with 46% of patients being completely dry. After 2 years, 56% of the urgency-frequency patients showed greater than 50% reduction in voids per day. After 1.5 years, 70% of 42 retention patients showed greater than 50% reduction in catheter volume per catheterization. We conclude that the Medtronic InterStim therapy for urinary control system is an effective therapy with sustained clinical benefit for patients with intractable symptoms of urinary urge incontinence, urgency-frequency, or retention.

(NB appears to be the same multicentre study U. Jonas et al above so cited as a single paper).

3. LEVEL 4: RETROSPECTIVE CASE SERIES

Sacral nerve stimulation for treatment of refractory urinary retention: long-term efficacy and durability, White WM, Dobmeyer-Dittrich C, Klein FA, Wallace LS., Urology. 2008 Jan;71(1):71-4. doi: 10.1016/j.urology.2007.08.034., Source: Department of Urology, University of Tennessee Medical Center, Knoxville, Knoxville, Tennessee 37920, USA. wwhite@mc.utmck.edu

Abstract

Objectives: To examine the long-term efficacy and durability of sacral nerve stimulation (SNS) for the treatment of refractory, nonobstructive urinary retention.

Methods: A retrospective study of all patients who underwent SNS with the InterStim device for refractory, non-obstructive urinary retention was performed. All patients had their history taken, underwent physical examination and urodynamic study, and completed a voiding diary before treatment with staged SNS. Patients with greater than 50% improvement in symptoms underwent implantable program device placement. Patients were followed up for evidence of postoperative complications, device failure, and treatment efficacy. Statistical analyses were performed.

Results: From June 1, 2000 to February 1, 2007, 40 patients were treated with SNS for refractory, non-obstructive urinary retention. Of the 40 patients, 29 had complete urinary retention (using clean intermittent catheterization), and 11 demonstrated incomplete retention (elevated postvoid residual urine volume). Of the 40 patients, 28 (70%) demonstrated greater than 50% improvement in symptoms and underwent implantable program device placement. At a mean follow-up of 40.03 +/- 19.61 months, 24 (85.7%) of 28 patients demonstrated sustained improvement of greater than 50%. Of the 28 patients, 4 (14.3%) had their InterStim device removed and 6 (21.4%) required revision. Among those with complete retention, significant improvement occurred in the number of catheterizations/day and the volume/catheterization (P <0.001). Among those with incomplete retention, significant improvement occurred in the postvoid residual urine volume (P <0.001).

Conclusions: At a mean follow-up of 40 months, 85.7% of patients with refractory, nonobstructive urinary retention demonstrated greater than 50% improvement in symptoms with SNS. For 911 patients, a statistically significant improvement in voiding parameters resulted.

4. LEVEL 5: EXPERT OPINION

Current Urology reports: Sacral nerve stimulation to treat nonobstructive urinary retention in women, Craig V. Comiter, September 2008 Volume 9, Issue 5 pp 405-411

Abstract

Non-obstructive urinary retention is an uncommon finding in women that may represent a difficult management problem for urologists and patients. Pharmacotherapy and urethral dilatation are rarely successful, and clean intermittent catheterization may be cumbersome. Those patients who cannot self-catheterize may be subjected to an indwelling catheter. Sacral nerve stimulation is a minimally invasive treatment for non-obstructive urinary retention, with 10 years of data documenting its long-term safety and efficacy. This minimally invasive treatment can restore satisfactory voiding in most patients and should be a routine part of treatment for this rare but important condition.

5. LEVEL 1: SYSTEMATIC REVIEW

Sacral nerve stimulation for faecal incontinence and constipation in adults, Mowatt G, Glazener CMA, Jarrett M, Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD004464. DOI: 10.1002/14651858.CD004464.pub2, Last updated May 23, 2007

Review Method: All randomised or quasi-randomised trials assessing the effects of SNS for faecal incontinence or constipation in adults.

Data collection and analysis: Two review authors independently screened the search results, assessed the methodological quality of the included studies, and undertook data extraction.

Main results: Three crossover studies were included. Two, enrolling 34 (Leroi) and two participants (Vaizey), assessed the effects of SNS for faecal incontinence, and one (Kenefick), enrolling two participants, assessed SNS for constipation.

In the study by Leroi, following the crossover period, participants, while still blinded, chose the period of stimulation they had preferred. Outcomes at different time points were reported separately for 19 participants who preferred the 'on' and five who preferred the 'off' period. For the group of 19, the median (range) episodes of faecal incontinence per week fell from 1.7 (0 to 9) during the 'off' period to 0.7 (0 to 5) during the 'on' period; for the group of five, however, the median (range) rose from 1.7 (0 to 11) during the 'off' period compared with 3.7 (0 to 11) during the 'on' period. Vaizey reported an average of six, and one, episodes of faecal incontinence per week during the 'off' and 'on' periods respectively. Leroi reported that four of 27 participants experienced an adverse event resulting in removal of the stimulator; Vaizey did not report adverse events.

For SNS for constipation, during the 'off' crossover period the participants experienced an average of two bowel movements per week, compared with five during the 'on' period. Abdominal pain and bloating occurred 79% of the time during the 'off' period compared with 33% during the 'on' period. No adverse events occurred.

Authors' conclusions: The very limited evidence from the included studies suggests that SNS can improve continence in selected people with faecal incontinence, and reduce symptoms in selected people with constipation. However temporary, percutaneous stimulation for a two-to-three week period does not always successfully identify those for whom a permanent implant will be beneficial. Larger, good quality randomised crossover trials are needed to allow the effects of SNS for these conditions to be assessed with more certainty.

6. LEVEL 3/4: DOUBLE BLIND CROSS-OVER STUDY

Sacral nerve neuromodulation for the treatment of lower bowel motility disorders, Kenefick NJ, Ann R Coll Surg Engl. 2006 Nov;88(7):617-23.

Abstract

Introduction: Incontinence and constipation are common and cause a high degree of physical, social and psychological impairment. Maximal conservative therapy may improve some patients but many remain symptomatic. Surgical options are often unsatisfactory, with variable result and further options are limited. Sacral nerve stimulation uses electrical stimulation applied to the sacral nerves, eliciting a physiological effect on the lower bowel, anal sphincter and pelvic floor, resulting in clinical benefit. The objective of this study was to investigate whether sacral nerve neuromodulation can improve patients with disorders of bowel motility, when current maximal treatment has failed and to investigate the underlying physiological mechanism of action.

Results: Incontinence: Nineteen patients, age 58 years (range, 37-71 years), with resistant incontinence for 6 years (range, 2-21 years) underwent stimulation. Continence improved in all at 24 months (range, 3-60 months), fourteen fully continent. Incontinent episodes decreased; 12 (range, 2-30) versus 0 (range, 0-4), $P < 0.001$. Urgency ($P < 0.01$) and quality of life improved ($P < 0.05$). Anal squeeze pressure ($P = 0.001$) and rectal sensation ($P < 0.01$) improved. Constipation: Four women, (aged 27-36 years) with resistant idiopathic constipation for 8-32 years underwent the first worldwide implants. Symptoms improved in all with temporary, and in three with permanent, stimulation at 8 months (range, 1-11 months). Bowel frequency increased: 1-5 versus 6-28 evacuations/3-weeks. Symptom scores and quality of life improved. Placebo effect: A double-blind, cross-over study was performed to examine placebo effect and efficacy. Once stimulation was removed, in a blinded manner, symptoms,

physiological parameters and quality of life measures rapidly returned to baseline levels. Autonomic neuromodulation: Sixteen patients, median age 59 years (range, 38-71 years), were studied at 27 months (range, 2-62 years) using laser Doppler flowmetry. Chronic stimulation was at 2.8 V (range, 0.3-3.9 V). Median flux differed between none and chronic stimulation (P = 0.001). Step-wise increments caused an immediate, dose-dependent rise in flux (P < 0.0001) up to 1.0 V.

Conclusions: This research provides strong evidence that sacral nerve stimulation can improve patients with resistant incontinence and shows proof-of-concept for the treatment of constipation. The effect is unlikely to be due to placebo and the mechanism is rapidly reversible and involves a dose-dependent effect on the autonomic nerves.

7. LEVEL 4: RETROSPECTIVE REVIEW

Sacral neuromodulation therapy: a promising treatment for adolescents with refractory functional constipation, van Wunnik BP, Peeters B, Govaert B, Nieman FH, Benninga MA, Baeten CG., Dis Colon Rectum. 2012 Mar;55(3):278-85. doi: 10.1097/DCR.0b013e3182405c61.

Abstract

Background: Sacral neuromodulation therapy has been successfully applied in adult patients with urinary and fecal incontinence and in adults with constipation not responding to intensive conservative treatment. No data, however, are available on sacral neuromodulation therapy as a treatment option in adolescents with refractory functional constipation.

Objectives: This study aimed to describe the short-term results of sacral neuromodulation in adolescents with chronic functional constipation refractory to intensive conservative treatment.

Design: This is a retrospective review.

Setting: This study took place at the Department of Surgery, Maastricht University Medical Centre, The Netherlands.

Patients: Thirteen patients (all girls, age 10-18 years) with functional constipation according to the ROME III criteria not responding to intensive oral and rectal laxative treatment were assigned for sacral neuromodulation.

Main Outcome Measures: When improvement of symptoms was observed during the testing phase, a permanent stimulator was implanted. Patients were prospectively followed up to at least 6 months after implantation of the permanent stimulator by interviews, bowel diaries, and Cleveland Clinic constipation score. Improvement was defined as spontaneous defecation ≥ 2 times a week.

Results: At presentation, none of the patients had spontaneous defecation or felt the urge to defecate. All patients had severe abdominal pain. Regular school absenteeism was present in 10 patients. After the testing phase, all but 2 patients had spontaneous defecation ≥ 2 times a week with a reduction in abdominal pain. After implantation, 11 (of 12) had a normal spontaneous defecation pattern of ≥ 2 times a week without medication, felt the urge to defecate, and perceived less abdominal pain without relapse of symptoms until 6 months after implantation. The average Cleveland Clinic constipation score decreased from 20.9 to 8.4. One lead revision and 2 pacemaker relocations were necessary.

Limitations: This study is limited by its small sample size, single-institution bias, and retrospective nature.

Conclusion: Sacral neuromodulation appears to be a promising new treatment option in adolescents with refractory functional constipation not responding to intensive conservative therapy. Larger randomized studies with long-term follow-up are required.

8. LEVEL 4: CASE SERIES

Sacral neuromodulation for the management of severe constipation: development of a constipation treatment protocol, Sharma A, Liu B, Waudby P, Duthie GS., Int J Colorectal Dis. 2011 Dec;26(12):1583-7. doi: 10.1007/s00384-011-1257-x. Epub 2011 Jun 30.

Abstract

Background: Constipation is a common multifactorial gastrointestinal symptom with quality of life implications. Sacral neuromodulation has been used in the management of severe constipation with

mixed results. The aim of this study was to review our experience of sacral neuromodulation as a treatment for chronic constipation and develop a chronic constipation management protocol.

Methods: In patients with severe constipation, failure of conservative management including biofeedback and rectal irrigation were considered for neuromodulation. Temporary stimulation lead was placed in the sacral foramen of eligible patients and pre and post stimulation bowel diaries were compared. Patients with ≥50% improvement in bowel diaries had permanent implant. Patients were followed up at 2 and 4 weeks, 3, 6, and 12 months, and then yearly with bowel diaries.

Results: Temporary neuromodulation wires were implanted in 21 patients (20 female). Significant bowel diary improvement was seen in 12 (57%) patients ($p < 0.01$). Eleven permanent implants have been performed. Improvement in symptoms was lost in one patient. No major side effects were observed. Three patients have had reoperations (one wire fracture, one reposition of battery, and one poor initial lead placement). Improvements in bowel diaries have been maintained over a median follow-up period of 38 months (18-62 months).

Conclusion: Sacral neuromodulation can provide long-term symptom relief in selected patients with severe constipation. Sacral neuromodulation should be incorporated into the treatment algorithm for chronic constipation.

9. LEVEL 3: CASE SERIES

Permanent sacral nerve stimulation for treatment of idiopathic constipation, Kenefick NJ, Nicholls RJ, Cohen RG, Kamm MA., Br J Surg. 2002 Jul;89(7):882-8.

Abstract

Background: Constipation can usually be managed using conservative therapies. A proportion of patients require more intensive treatment. Surgery provides variable results. This paper describes an alternative approach, in which the neural control of the bowel and pelvic floor is modified, using permanent sacral nerve stimulation.

Methods: Four women (aged 27-36 years), underwent temporary and then permanent stimulation. All had idiopathic constipation, resistant to maximal therapy, with symptoms for 8-32 years. Clinical evaluation, bowel diary, Wexner constipation score, symptom analogue score, quality of life questionnaire and anorectal physiology were completed.

Results: There was a marked improvement in all patients with temporary, and in three with permanent, stimulation. Median follow-up was 8 (range 1-11) months. Bowel frequency increased from 1-6 to 6-28 evacuations per 3 weeks. Improvement occurred, at longest-follow-up, in median (range) evacuation score (4 (0-4) versus 1 (0-4)), time with abdominal pain (98 (95-100) versus 12 (0-100) per cent), time with bloating (100 (95-100) versus 12 (5-100) per cent), Wexner score (21 (20-22) versus 9 (1-20)), analogue score (22 (16-32) versus 80 (20-98)) and quality of life. Maximum anal resting and squeeze pressures increased. Rectal sensation was altered. Transit time normalized in one patient.

Conclusion: Permanent sacral nerve stimulation can be used to treat patients with resistant idiopathic constipation.

10. LEVEL 5: REVIEW

Status of sacral neuromodulation for refractory constipation, C. G. M. I. Baeten, Volume 13, Issue Supplement s2, pages 19–22, March 2011

Abstract

Aim: This review article aims to provide a brief update on the current data on and position of sacral neuromodulation (SNM) in the specialized management of refractory idiopathic constipation.

Method: Published evidence from PubMed and our own unpublished data on SNM treatment for refractory idiopathic constipation were used for this evaluation.

Results: Seven studies were found in PubMed that covered this topic. The main focus was on the most recently published multicentre nonrandomized European trial. Summary data from our unpublished study on constipation in children are also included.

Conclusions: The use of SNM in the treatment of idiopathic constipation is still in its early phase and while the available efficacy and safety data are limited, they show promising results. As there are few

alternatives for this difficult patient group, it is worth offering a percutaneous nerve evaluation (PNE) test, which is known to be a good predictor of post implant treatment success.

11. LEVEL 1: EVIDENCE BASED GUIDELINE

NICE IPG536: Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention, Published: 25/11/15 (Added at review: Jan 2016)

Current evidence on the safety and efficacy of sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

12. LEVEL 1: SYSTEMATIC REVIEW

Sacral nerve stimulation for faecal incontinence and constipation in adults, Thaha MA et al The Cochrane Library 2015, Issue 8 (Added at review: Jan 2016)

This review evaluated the published evidence for the use of SNS for patients with faecal incontinence or constipation from six trials of SNS for faecal incontinence (219 participants) and two trials of SNS for constipation (61 participants). Two of the faecal incontinence trials had a 'parallel group design', which means that one group of participants received SNS and the other control group did not receive SNS throughout the trial. The remaining six trials had a 'crossover design', in which the participants experienced equal periods with stimulation 'off ' then 'on', or vice versa. The level of stimulation was such that participants could not tell whetherthe system was 'on' or 'off '.

SNS for constipation: In one trial assessing SNS for constipation, two participants reported an increase of 150% in the frequency of passing stools per week, and time with abdominal pain and swelling went down from 79% during the 'off ' period to 33% during the 'on' period. However, in the much larger second trial assessing SNS for constipation, in 59 participants SNS did not improve frequency of bowel movements.

Authors' conclusions: The limited evidence from the included trials suggests that SNS can improve continence in a proportion of patients with faecal incontinence. However, SNS did not improve symptoms in patients with constipation. In addition, adverse events occurred in some patients where these were reported. Rigorous high quality randomised trials are needed to allow the effects of SNS for these conditions to be assessed with more certainty.

Appendix 2 – Diagnostic and Procedure Codes

Sacroneuromodulation for Urinary Retention and Constipation
GM029 & GM064

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

GM029 & GM064 - Sacral Neuromodulation for Urinary Retention & Constipation Policy	
Implantation of neurostimulator into peripheral nerve	A70.1
Maintenance of neurostimulator in peripheral nerve	A70.2
Removal of neurostimulator from peripheral nerve	A70.3
Insertion of neurostimulator electrodes into peripheral nerve	A70.4
In addition to one of the above OPCS-4 codes the following site code would be assigned:	
Temporary operations; would be assigned in addition to:	Y70.5
Sacral nerve	Z11.2
With the following ICD-10 diagnosis code(s):	
Constipation	K59.0
Other specified urinary incontinence	N39.4
Faecal incontinence	R15.X
Retention of urine	R33.X

Appendix 3 – Version History

Sacroneuromodulation for Urinary Retention and Constipation
GM029 & GM064

The latest version of this policy can be found here: GM Sacroneuromodulation for Urinary Retention and Constipation policy

Version	Date	Summary of Changes
0.1	12/05/2014	Initial draft for consideration by the GM EUR Steering Group • Draft Policy approved for consultation by GM EUR Steering Group on 21/05/2014. • Policy published for consultation from 09/07/2014 to 03/09/2014.
0.2	25/09/2014 17/09/2014	Amendments made by GM EUR Steering Group on 17/09/2014 following review of feedback from the consultation: • Inclusion of additional criteria in section 4, mandatory criteria to include: 'cases where Fowler's Syndrome is the expected diagnosis which has been proved by EMG, sacral neuromodulation will be approved.' • The title of the policy is changed to sacral neuromodulation for urinary retention and constipation. • Wording changed in section 2, definition to reflect that this is not an evolving technology; rather it is the range of uses that are evolving. • Section 9, rationale behind the policy statement also amended to reflect that this is not an evolving technology. Approved by GM EUR Steering Group, subject to above amendments.
0.3	08/10/2014	Branding change following creation of North West CSU on 1/10/2014.
1.0	17/09/2014	Approved by GM EUR Steering Group – amendments have been made.
2.0	20/01/2016	Policy reviewed by GM EUR Steering Group and agreed no material changes necessary to the policy. • Following paragraph added under Policy Exclusions: *'Sacroneuromodulation as part of an externally funded trial or a locally agreed pathway of care is excluded from this policy'* • Wording for date of review changed. • Section 8 - Adherence to NICE Guidance Section updated to: *'This policy is compliant with NICE IPG 536: Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention (published 25/11/15)'* • Section 9 - Funding Mechanism updated to read: *'Funding will be available on an individual patient basis, for those patients, who meet NICE IPG 536; with a diagnosis of Fowler's Syndrome or where evidence of exceptionality is demonstrated. Individual Prior Approval should be sought in line with the procedures described in the Greater Manchester Effective Use of Resources Operational Policy.'* • Evidence review updated following review.
2.1	05/04/2016	• List of diagnostic and procedure codes in relation to this policy added as Appendix 2. • Policy changed to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.
3.0	17/01/2018	Policy reviewed by GM EUR Steering Group:

		• Policy moved to new template • Policy Inclusion Criteria: *'Sacroneuromodulation is considered a developmental treatment in relation to urinary retention and constipation and will only be commissioned:* • *for Fowler's Syndrome (the diagnosis should be confirmed by EMG)* • *as part of a commissioned trial.* *Funding will be available on an individual patient basis, for those patients, who meet NICE IPG 536; with a diagnosis of Fowler's Syndrome or where evidence of exceptionality is demonstrated.'* amended to: *'Funding will be available on an individual patient basis for those patients who meet NICE IPG 536 who:* • *have a confirmed diagnosis of Fowler's Syndrome (diagnosis should be confirmed by EMG)* ***OR*** • *have intractable non-obstructive urinary retention* • Commissioning Statement: Sentence added under title to read: *'There are a number of variations of the terminology, including sacral neuromodulation and sacral nerve stimulation. All variations relating to either urinary retention or to constipation are covered by this policy'*. • Glossary: Under 'Fowler's Syndrome' typo amended from *'if'* to *'is'* • Date of Review: Standard wording on next review added to state *'5 years'* The changes were not considered to be material and therefore it was not necessary for the revised policy to go back through the governance process again.
3.1	28/01/2019	• Branding changed to reflect change of service from Greater Manchester Shared Services to Greater Manchester Health and Care Commissioning. • Links updated as documents have all moved to a new EUR web address. • Commissioning Statement: o *'(Alternative commissioning arrangements apply)'* added after Policy Exclusions o *'Best Practice Guideline'* section added