Sacral Neuromodulation (SNM) for overactive bladder symptoms and for non-obstructive voiding dysfunction

Patient Information
Sacro Neuromodulation

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About this leaflet
There is a lot of important information in this leaflet. Please read it carefully, not necessarily in one session. On the sheet provided (towards the back) write down any questions you have and we can discuss them with you next time we see you.

It is important you understand why we are recommending sacral nerve stimulation, what it involves and what the risks are. We will also explain alternatives to this treatment within this leaflet.

It is very important that you understand what we will be doing. Any operation can be risky and should not be undertaken without considerable thought.

This leaflet describes what overactive bladder syndrome (OAB) and non obstructive voiding dysfunction (VD) are. It then describes what alternatives to sacral nerve stimulation we can offer. There are a number of surgical options to manage OAB and VD. Each has its own good points and bad points and these will be mentioned within this leaflet. Sometimes a particular operation in a particular situation is not suitable. We will give you guidance on this.

What is overactive bladder?
Overactive bladder (OAB) is a condition in which the sufferer complains of urinary urgency (a sudden strong desire to pass urine which is difficult to ignore) usually with:
- Frequency, going to the toilet more often than before
- Nocturia, getting up at night to pass urine

And sometimes with:
- Urgency urinary incontinence, the involuntary leakage of urine associated with urgency
Treatments you should try before considering surgery for OAB:

- **Fluid management**: ensuring you drink between 1500-2000ml (2-3 pints) of fluids per day. No more, no less and spreading your fluids throughout the day. Avoid alcohol, caffeine and fizzy drinks.

- **Bladder retraining**: this can be taught by your continence advisor. The time interval between trips to the toilet to urinate is gradually increased and you are taught coping strategies to help curb the sensation of needing to urinate.

- **Pelvic floor muscle training (PFMT)**: The pelvic floor muscle runs from the coccyx at the back to the pubic bone at the front and off to the sides. This muscle supports your pelvic organs (uterus and bladder) and your bowel. Any muscle in the body needs exercise to keep it strong so that it functions properly. PFMT can strengthen the pelvic floor and help control the leakage due to urge incontinence. PFMT are best taught by an expert who is usually a physiotherapist. These exercises have no risk and even if surgery is required at a later date, they will help your overall chance of becoming continent.

- **Medication**: This includes, but is not limited to, medicines which block the transmission of messages in the nerves which supply the bladder muscle.

Alternative surgical options to sacral neuromodulation (SNM) for OAB:

- **Botox injections to the bladder**: A camera (cystoscope) is inserted to your bladder. Under direct vision, a series of injections of the Botox are put into the bladder wall to relax it. This will reduce the ability of the bladder muscle to contract, so reducing your symptoms. It offers a 75% chance of improvement to your symptoms, but will gradually wear off over four to nine months and therefore the procedure will need to be repeated. There is a small risk of developing urinary retention (being unable to empty your bladder) with this procedure (15%). If this happened you will need to be taught how to empty the bladder with a thin plastic tube called an intermittent catheter one to four times a day until the effect of the Botox wears off.

- **Augmentation cystoplasty**: This is a major surgical procedure which involves patching the bladder with a loop of bowel to increase its capacity and make it able to store more urine. The improvement in OAB is 50-90%, but it is associated with the following risks: Recurrent urinary tract infections 37%, voiding difficulty 37%, problems associated with needing to self-catheterise 11%, bladder stone formation 38%, change in bowel function-which can include frequency, diarrhoea or incontinence 11-25%, Metabolic disturbances 16% and a small risk of cancer in the bowel loop used to patch up the bladder. Therefore these patients will require life long follow up.

- **Urinary diversion**: This means re-routing the urine away from the usual outlet through the urethra (wee pipe). It usually involves isolating a segment of bowel to act as a reservoir for urine instead of the bladder and then connecting this bowel loop to the skin in the tummy wall. The patient has to pass a catheter into the “new bladder” via the tube connecting it to the tummy wall to empty it regularly. Little information is available on this operation, but complications are common and include infection, stoma related problems and the need for surgical revision.
Life long follow up is recommended. The National Institute for Clinical Excellence (NICE) recommends that this procedure is only considered after consideration of the above options.

- **Detrusor myomectomy**: There is not enough evidence of benefit from this operation and therefore it is not currently recommended.

**What is non-obstructive voiding dysfunction:**
This refers to when a person cannot empty their bladder in the normal way, despite there being no blockage in the urine pipe. This means the bladder never empties properly and can result in urine leakage, recurrent infections, urinary frequency and may affect kidney function.

**Alternatives to SNM for non-obstructive voiding dysfunction:**
The most commonly used alternative is catheterisation of the bladder. The best way to do that is to teach the patient to pass a small tube (intermittent catheter) into the bladder after passing urine / attempting to pass urine, in order to make sure that the bladder is fully empty. Most patients manage this well. It is associated with a small risk of infection. The other option is having a catheter in the bladder permanently to drain it, preferably via a small hole in the lower tummy wall or less preferably via the urethra (wee pipe). Having permanent catheterisation is associated with a risk of infection, blockage, leak and stone formation.

**What does the procedure of sacral neuromodulation involve?**
SNM is a two stage procedure; the first stage is a temporary test for two weeks using an external battery. This test assesses if your symptoms would respond to electric stimulation. The second stage, permanent implantation, will only be offered to those whose symptoms greatly improve (more than 50% improvement) during the test procedure. During permanent implantation a permanent battery is implanted in the upper part of the buttock.

Prior to any treatment you will be asked to complete a pre operative bladder diary and an electronic pelvic assessment questionnaire (e-PAQ) to allow us to assess how severe your symptoms are. You will then be given a date for the test procedure.

**How is the test procedure performed?**

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The dotted line is where the lower part of the back bone is under the skin in the lower back / upper buttock area.
The operation is performed under sedation or a general anaesthetic. You will be laid on your front to allow access to your back for the wire insertion. A local anaesthetic is given into the skin at the base of your back. A special introducer needle is then positioned. This goes through the S3 foramen, a naturally occurring hole in your sacrum (lower part of the back bone) and sits close to the S3 nerve.

The test electrode is inserted through the introducer needle and it exits through the skin at the base of your back. The introducer needle is removed leaving the electrode in your back. The test electrode is held in place with a dressing and attached to the test stimulator.

Once you have fully recovered from your anaesthetic your electrode will be turned on and you will be instructed on how to use the stimulator. You will go home with the test wire in place for two weeks. During the test you will need to complete a detailed bladder diary. The results of the diary will determine if the test has been successful and if you are suitable for a permanent implant.

You will also be unable to take a shower or bath during the test as the dressing on your back should not get wet. Instead you may wash at the sink or hand shower avoiding the dressing. We also ask you to abstain from any rigorous exercise or excessive movement as the test electrode could move resulting in test failure.

**After the test**

After two weeks you will attend the outpatients to have your test electrode removed. The dressing is taken off and the electrode is gently removed in the outpatient clinic.

We will ask you to repeat the ePAQ questionnaire and collect your completed bladder diary. This will tell us whether your symptoms were improved during the test. Your symptoms will go back to how they were prior to the test once the electrode is removed. Your consultant will then discuss with you if you are suitable for permanent implantation or not. If you are, you will be required to sign a consent form and will be put on the waiting list for the permanent procedure.

**The permanent implant procedure**

You will be asked to come to the hospital on the morning of the procedure and most patients are discharged from hospital the same day. The permanent implant procedure is similar to the test procedure except the electrode is buried under the skin attached to the neuromodulator (battery) which is inserted through a small cut in the buttock.

When you wake from your anaesthetic you will have two wounds covered with dressings. A small 1cm cut at the base of your back where the electrode was inserted and a 3-4cm cut on your buttock where the implant is buried. You will get pain at the operation site; you are advised to take regular painkillers for this. The implant will not be turned on before you are discharged. You will be given an outpatient appointment to have your implant turned on approximately two weeks after your operation. You will need to arrange for your dressings to be changed a couple of times over the next two weeks. If you have any problems after your surgery you must contact your surgeon’s secretary for advice.
Turning on your permanent implant

You will be asked to return to the outpatient clinic to have your implant switched on. Your wound will be inspected and if it is sufficiently healed the dressing will be removed. You will then have your implant programmed to try and mimic the sensation you had with your test procedure. You will be shown how to use your icon handset (remote control) to increase or decrease the stimulation and switch the implant on and off. Once you are happy with this you can go home.

Follow up

You will be followed up one month after your implant has been switched on to check your programme and to ensure you are entirely happy using your icon handset and that your symptoms are controlled. If they are not, you will be seen for a change to your program.

If your symptoms are well controlled we will see you again at six months then on a yearly basis lifelong to ensure that your device is working correctly and to check the battery life. At these appointments you will need to complete a bladder diary and ePAQ questionnaire so we can monitor your symptoms. However we have an open door policy and you are free to contact the specialist nurse at any time for advice, support and programming queries.

Facts and figures

Sacral Neuromodulation is the only surgical treatment of OAB that is backed up by randomised controlled trials and therefore it is the first recommended surgical treatment by the NICE guidelines. Unlike Botox, SNM offers a long term approach to managing your OAB symptoms.

If successful, the implant usually lasts for approximately six years before the battery needs to be replaced. However this can be less than six years depending on how high your program settings are. You can get back to normal daily activities (apart from strenuous and stretching exercises) three months after you have had your permanent implant. You are in control of your therapy as you have your own programmer to adjust the settings.

- SNM is suitable for approximately 70% of all people who undergo a test procedure.
- Patients who have minimal medical problems have better results with SNM.
- The younger you are the better result you may get from SNM however the longer you will need the implant.

For OAB patients:

- Approximately 50% of patients with an implant will be completely free from leakage accidents and 80% will have at least 50% improvement in the amount of leakage accidents.
- Approximately 56% of patients with an implant will have a reduction in the frequency of their trips to the toilet to urinate to around 4 to 7 times per day.

For patients with non obstructive voiding dysfunction:

- Around 64% will see the average volume of urine they pass double in size.
- Around 69% of patients who use a catheter before their implant can discontinue catheter use.
General risks of surgery

- **Anaesthetic risk.** This is very small unless you have specific medical problems. This will be discussed with you.

- **Haemorrhage.** There is a small risk of bleeding with any operation. This is extremely rare with the temporary procedure and fairly rare with the permanent procedure. The risk from blood loss is reduced by knowing your blood group and having blood to give to you if necessary. It is rare that we have to transfuse patients after their operation.

- **Infection.** There is a small risk of infection at any of the cut sites. In some circumstances the implant may have to be removed due to infection and you may have to wait until the infection settles before repeat implantation can be considered. A significant infection is rare but you are more at risk from infection if you are diabetic. The risk of infection is reduced by routinely giving antibiotics with surgery.

- **Deep Vein Thrombosis (DVT).** This is a clot in the deep veins of the leg. The overall risk is at most 4%. Occasionally this clot can migrate to the lungs which can be very serious and in rare circumstances it can be fatal (less than 1% of those who get a clot). DVT can occur more often with major operations around the pelvis and the risk increases with obesity, gross varicose veins, infection, immobility and other medical problems. The risk is reduced by using special stockings or injections to thin the blood slightly (heparin).

Summary of the risks in sacral nerve stimulator implantation

- **Operative risks:** In addition to the previous risks, there is a very small (1%) risk of injury to bowel or major vessels requiring a laparotomy (open surgery) to put things right.

- **Re-operation:** Up to 33% of patient will require another procedure related to SNM: 15% are to relocated/replace the implant, 9% to remove the implant and rest are due to device problems.

- **Infection:** 5% of patients (higher in diabetic patients) may need to have the implant removed due to infection.

- **Pain:** Up to 24% of patients may experience discomfort or unpleasant stimulation at the site of the implant or elsewhere.

- **Lost efficacy:** 30% of those who have an implant will not have the same favourable response they had with the temporary external battery. For those in whom the implant works initially up to 8% of them may experience a decrease in efficacy overtime.

- **Wound problems:** Up to 7% can experience wound discharge, bleeding or defective healing. These are usually easy to deal with.

- **Adverse bowel function:** Most patients experience coincidental improvement in their bowel function, but 6% may experience an undesired change in their bowel function.
Further information

You may find the address and websites useful to obtain more information. We can however bear no responsibility for the information they provide.

- Bladder and Bowel Foundation
  SATRA Innovation Park, Rockingham Road
  Kettering, Northants, NN16 9JH
  Nurse helpline for medical advice: 0845 345 0165
  Counsellor Helpline: 0870 770 3246
  General enquiries: 01536 533255
  Fax: 01536 533240
  mailto:info@bladderandbowelfoundation.org
  http://www.bladderandbowelfoundation.org/

- www.nice.org.uk/guidance/IPG64/PublicInfo/pdf/English

Things I need to know before I have my operation

Please list below any questions you may have, having read this booklet, that will help you decide whether you want an operation.

1)............................................................................................

2)............................................................................................

3)............................................................................................

4)............................................................................................

5)............................................................................................

Describe what your expectations are from surgery. This is very important.

1)............................................................................................

2)............................................................................................

3)............................................................................................

4)............................................................................................

5)............................................................................................
We hope you have found this information helpful. Please remember our staff will be happy to answer any questions you have about any aspect of your care and welcome any comments about this leaflet.

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<thead>
<tr>
<th>The James Cook University Hospital</th>
<th>The Friarage Hospital</th>
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</thead>
<tbody>
<tr>
<td>Appointments Desk: 01642 854861 / 282714 / 854883</td>
<td>Appointments Desk: 01609 764814</td>
</tr>
<tr>
<td>Gynaecology Outpatients Dept. (Including Pre-admission Service): 01642 854243</td>
<td>Gynaecology Outpatients Dept: 01609 764814</td>
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<tr>
<td>Surgical Admissions Unit: 01642 854603</td>
<td>Surgical Admissions Unit Reception: 01609 764847 Nursing Staff: 01609 764657</td>
</tr>
<tr>
<td>Women’s Health Unit / Ward 27: 01642 854527</td>
<td>From 7am Mondays until 5pm Fridays, Allen POS.D.U.: 01609 764405</td>
</tr>
<tr>
<td>Secretary to Mr Khunda: 01642 854681</td>
<td>From 5pm Fridays until 7am Mondays, Allerton Ward: 01609 764404</td>
</tr>
</tbody>
</table>

Author: The Gynaecology Medical and Nursing Team at The James Cook University and Friarage Hospitals.