

FIRST REPORTED EXPERIENCE OF SACRAL NERVE STIMULATION IN PATIENTS WITH FAECAL INCONTINENCE USING THE AXONICS® MINIATURIZED, RECHARGEABLE NEUROMODULATION SYSTEM.

Hypothesis / aims of study

Sacral nerve stimulation (SNS) is an effective treatment for patients with severe faecal incontinence refractory to conservative treatments. To date, SNS has utilized a non-rechargeable device which requires replacement every 4-5 years. A new rechargeable SNS system, 60% smaller in size and with an estimated battery longevity of over 15 years is now available. This device, the Axonics r-SNM System™, has regulatory approval for use in Europe and Canada. The aim of this case series was to evaluate the handling and short-term benefits of a rechargeable SNS device in a small group of patients prior to introduction into general clinical practice. This was performed at a University hospital with extensive experience in the use of SNS for bowel control.

Study design, materials and methods

Patients with faecal incontinence that met UK NICE guidance for SNS were offered the choice of a non-rechargeable or rechargeable SNS device. Potential advantages and disadvantages of each system were explained to the patient as part of the consent process. Perceived advantages of the rechargeable device related to its smaller size (a potential reduced risk of infection and device related site pain) and longer battery life (reduced need for replacement surgery) with the caveat that battery charging was required for up to one-hour per week. Advantages of the non-rechargeable system related to its established therapeutic benefits and safety profile compared to the rechargeable system in which these factors are yet to be verified.

Symptom severity at baseline and at three months post implantation was recorded by bowel diary and St Mark's continence score. Evaluation of patient preference for device type was recorded. All patients underwent percutaneous nerve evaluation under general anaesthesia. In those that exhibited a good neurophysiological response (anal bellows +/- toe flexion at <3mA) a quadripolar tined lead and pulse generator were implanted. Follow-up at one and three months was performed. Effectiveness data in addition to morbidity and side-effects from the therapy were recorded. Treatment success was defined by a >75% reduction in episodes of faecal incontinence.

Results

Five of six consecutive patients being considered for SNS chose the rechargeable SNS system. Patient preference to have the rechargeable device related to its smaller size and potential for fewer future surgical interventions. All five patients demonstrated a good physiological response to percutaneous evaluation and were implanted with the rechargeable device. On programming, the sensory threshold to stimulation was <2mA in all patients. There were no short-term complications associated with device implantation.

All patients reported a good response to therapy at one month post-implantation. The St Mark's continence score was reduced from a mean (\pm SD) of 18 (\pm 1.6) at baseline to 5 (\pm 2.5) at one-month. At three months, four patients continued to benefit from therapy. One patient reported reduced efficacy having suffered two major incontinent episodes. This patient was found to be utilizing a very low stimulation amplitude and was encouraged to stimulate at higher level. Data regarding this patient's outcome is awaited. Recharging was performed at a median (range) of 7 (7-10) days with no patient requiring greater than 60 minutes per charging session. No patient reported any problems with recharging the device, in some cases charging was achieved whilst the patient was mobile and there were no therapy related side-effects.

Interpretation of results

SNS using a rechargeable device appears to have satisfactory efficacy. The numbers of patients in this case series however are small and therefore comparison with published data of non-rechargeable device clinical outcomes is not possible. There were no short-term complications associated with surgery or device operation. Recharging does not appear to be a burden to patients undergoing the therapy.

Concluding message

SNS using a rechargeable device has a potential clinical and cost benefit due to the reduction in need for future surgical procedures. Whilst battery change is not the sole reason for revision surgery, the smaller size of the Axonics r-SNM System may result in less risk of device related site pain and associated surgical intervention. Post-marketing monitoring to ensure reliability, safety and efficacy of the new device is imperative.

Disclosures

Funding: No grant or specific. Devices supplied and implanted as part of NHS neuromodulation clinical service. **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** New device meets regulatory requirements for use in humans (CE mark) and is available commercially. Case study reports on first use in humans for faecal incontinence as part of a service review. Device was discussed at new procedures advisory group and as device is seen as a replacement for an existing product applying the same therapy (electrical stimulation) ethical approval was not required. **Helsinki:** Yes **Informed Consent:** Yes