NICE advice

Axonics sacral neuromodulation system for faecal incontinence

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Axonics sacral neuromodulation (SNM) system. It is intended for use in faecal incontinence.
- The **innovative aspects** are that it is designed to need less frequent surgical replacement than the comparable non-rechargeable device currently used as standard care.
- The intended **place in therapy** is as an alternative to non-rechargeable SNM devices in people with faecal incontinence, who would be offered SNM in line with current NICE guidelines.
- The **main points from the evidence** summarised in this briefing are from 2 single-arm observational studies and 1 case series involving a total of 62 people with faecal incontinence. They show that Axonics SNM system may be effective, and that most people were satisfied with rechargeable therapy. Axonics SNM system was not compared with any other treatment.

- **Key uncertainty** around the technology is that the available evidence is limited in quantity and quality. Well-designed, comparative studies with larger numbers of people and longer follow up would be helpful to confirm equivalence to standard care in people with faecal incontinence.
- The **cost** of Axonics SNM system is £475 for the trial phase, £10,160 for a permanent implant and £7,000 for a replacement implant (all excluding VAT). A standard non-rechargeable SNM device costs up to around £10,000 depending on the type of temporary stimulation used and around £6,000 for a replacement implant (all excluding VAT).

The technology

Axonics sacral neuromodulation (SNM) system (Axonics Modulation Technologies, Inc.) stimulates a sacral nerve root (normally the S3 sacral nerve root) through an implantable pulse generator implanted subcutaneously in the upper buttock. Lead electrodes implanted through the corresponding sacral foramen transmit pulses from the stimulator to the sacral nerves. The stimulator is powered by a rechargeable battery which the company claim has an expected life span of 15 years or more.

A handheld remote control activates the stimulator, adjusts the stimulation amplitude, and checks the battery status. A wireless charger, placed on the skin over the implanted stimulator, is used to charge the stimulator. The company claims that the battery needs recharging every 1 to 2 weeks for 30 minutes to 1 hour. The implanted device is programmed by a clinician in an outpatient setting using a portable tablet.

Before permanent implantation, a temporary trial of SNM is recommended to assess response to therapy. Using the external stimulator, 2 different trial stimulation techniques can be done; a percutaneous nerve evaluation test using the non-tined single-contact temporary lead or a first stage tined lead test using the permanent tined lead. The company also offers kits containing all surgical tools needed for a percutaneous nerve evaluation test and a tined lead implant at extra cost.

Axonics SNM system can be used to treat symptoms of overactive bladder, faecal incontinence and urinary retention. NICE has published medical technologies guidance on the use of Axonics SNM system for treating refractory overactive bladder syndrome. This briefing is focused on the use of Axonics SNM system for treating faecal incontinence only.

Innovations

According to the company, the rechargeable battery that powers the stimulator has an expected lifespan of at least 15 years, which is longer than the comparable non-rechargeable device currently used as standard care. It is designed to reduce the number of invasive battery replacement procedures which would typically be needed around every 5 years with a non-rechargeable system. The stimulator is compatible with MRI and is smaller than existing non-rechargeable SNM devices, making it more suitable for people with a low body mass index.

Current care pathway

Adults with faecal incontinence will usually start treatment with a combination of conservative interventions (including dietary changes, addressing bowel habits, identifying coping strategies and medication) followed by specialist conservative management (such as pelvic floor muscle training, bowel retraining, specialist dietary assessment and management, biofeedback, electrical stimulation and rectal irrigation) if symptoms persist. If faecal incontinence continues after conservative management, specialist assessments may be done to identify possible causes and assess the person's suitability for surgery. Surgical treatments include repairing or tightening the sphincter (sphincteroplasty), or a colostomy (for severe uncontrolled faecal incontinence). Neosphincter surgery (graciloplasty or an artificial anal sphincter) may be considered, although these procedures are now very rarely done in the UK.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on faecal incontinence in adults recommends that SNM therapy should be considered in people with faecal incontinence in whom sphincter surgery is deemed inappropriate. The guideline states that people should be offered sacral nerve stimulation based on their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success.
- NICE's interventional procedures guidance on sacral nerve stimulation for faecal incontinence suggests that SNM therapy is an option that is typically offered as a surgical treatment for most patients in whom sphincter repair is inappropriate. The guidance also states that the procedure should only be done in specialist units by clinicians with a particular interest in the assessment and treatment of faecal incontinence.

Population, setting and intended user

Axonics SNM system would be used instead of non-rechargeable SNM systems in line with existing guidelines for faecal incontinence. Faecal incontinence is an inability to control bowel movements, resulting in involuntary soiling. It may result from degeneration of the anal sphincter, spinal injury or other neurologic disorders. Faecal incontinence may also happen for no known reason. The condition is associated with a high level of physical and social disability. If left untreated, the person may end up wearing pads to control the condition. It is estimated that up to 1 in 10 people will be affected by faecal incontinence during their lives.

Therapy with Axonics SNM system would be started by secondary care multidisciplinary teams including surgeons, specialist nurses and physiotherapists, and implanted by surgeons specialising in bowel dysfunction. As with other SNM devices, patient selection is guided by a positive response to a trial of tined lead testing or percutaneous nerve evaluation.

After implantation, people with the implant will use the remote control to adjust the level of stimulation depending on symptom control and comfort. They will also recharge the stimulator when battery level is low (as shown by the patient remote control).

Costs

Technology costs

Axonics SNM system, including necessary consumables and accessories, costs £10,635 (excluding VAT) regardless of the type of temporary stimulation used. The cost of replacing the system, which the company estimates is needed at most every 15 years, is £7,000.

A full breakdown of component costs (excluding VAT) are provided below. All Axonics SNM system components are sold with a 12-month product warranty.

Components for the trial phase (basic evaluation) include:

- a trial lead and surgical tools (contains 1 percutaneous nerve evaluation [PNE] lead and all surgical tools needed for a PNE lead implant) at a cost of £300

- a single-use, disposable external stimulator (1 belt included) at a cost of £175.

Components for permanent implant include:

- a neurostimulator (expected battery life of more than 15 years) at a cost of £7,000
- a tined lead at a cost of £1,600
- a permanent lead implant kit (contains all surgical tools needed for a tined lead implant) at a cost of £500
- a patient remote control at a cost of £500
- a charging system (includes 1 belt and 9 adhesive carriers) at a cost of £560.

The costs associated with a permanent implant assume that the patient had a successful basic trial evaluation.

For an advanced trial evaluation, an additional £2,100 would be needed for the trial phase (trial lead and surgical tools [£300] are replaced with a tined lead with percutaneous extension [£1,900] and lead implant kit [£500]). However, the costs associated with permanent implant in these people would be £2,100 less because the tined lead and permanent lead implant kit would not be needed.

As well as the device costs, the average cost of implantation is £2,772 (average NHS reference costs 2018 to 2019 for HRG codes FF47Z [insertion of neurostimulator] and FF48Z [insertion of neurostimulator electrodes]).

Costs of standard care

A standard non-rechargeable SNM device, including necessary consumables and accessories, costs up to about £10,000 (excluding VAT) depending on the type of temporary stimulation used. The cost of replacing the system, which is typically needed around every 5 years because of battery depletion, is around £6,000. As well as the device costs for standard care, the average cost of implantation is £2,772 (NHS reference costs, 2018 to 2019).

Resource consequences

If adopted, Axonics SNM system would be used instead of a standard non-rechargeable

SNM device, without needing changes to the current pathway in which SNM therapy is currently delivered in the UK.

The initial costs of implanting Axonics SNM system are similar to current non-rechargeable systems and, assuming the system needs replacement less often, it could reduce costs for medium- to long-term treatment (more than 5 years).

The company claims the clinician programmer accessory, which consists of a touchscreen colour tablet with built-in stimulation capabilities, provides a superior user experience for the surgeon because it is designed to decrease programming time and the need for manufacturer support.

Regulatory information

Axonics SNM system is a CE marked class III medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Faecal incontinence is associated with the protected characteristics of age, disability, sex, and pregnancy. Axonics SNM system is contraindicated in people who cannot operate the device, which could include people with physical or mental impairment.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Three studies are summarised in this briefing. They include 2 prospective, single-arm, before-and-after observational studies and a case series, including a total of 62 people with faecal incontinence.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

Overall, the available evidence suggests that using Axonics SNM system can help reduce episodes of faecal incontinence and improve quality of life. It also suggests that the system is straightforward to charge and that most people are satisfied with their therapy. No unanticipated or serious device-related events were reported in any of the studies.

The evidence base for using Axonics SNM system in the treatment of faecal incontinence is limited. Available evidence comes from a total of 62 people in 2 single-armed studies (1 of which was not primarily designed to evaluate the effectiveness in the treatment of faecal incontinence) and a small case series. There is a lack of randomised trials and a lack of direct comparison between Axonics SNM system and the standard care alternative.

Clinical effectiveness in treating faecal incontinence has not been shown for longer than 2 years. An extended follow up would be desirable, given the intended duration of implant with the rechargeable SNM device.

Only 1 of the studies was exclusively done in the UK (Dudding 2017). This was a small, single-centre case series involving 5 people. Data from this study were published in a conference abstract only and could not be fully assessed for statistical or clinical significance. The ARTISAN-SNM study included 1 UK centre but the proportion of people with faecal incontinence from this UK study site was not reported. The remaining study (Jottard et al. 2020) was done in Belgium which may limit generalisability to the NHS. This study reports on a single-nonstaged procedure which differs to current clinical practice that recommends an external trial phase is done before having a permanent implant.

Jottard et al. (2020)

Study size, design and location

Fifteen people (aged 18 and over) with faecal incontinence in a prospective before-and-after observational study in Belgium.

Intervention and comparator

Axonics SNM System, no comparator.

Key outcomes

Most people (n=13, 87%) had a 50% or higher reduction in faecal incontinence episodes at 4 weeks (as documented in patient bowel diaries). Using Axonics SNM system was associated with a 75% reduction in weekly faecal incontinence episodes at 4 weeks and a 79% reduction at 6 months (from a median of 8 at baseline to 1.5 at 4 weeks and at 6 months, p=0.001 for both time points). Twelve of the 13 people (92%, per protocol) who had a 50% or higher reduction in faecal incontinence episodes at 4 weeks, also had a 50% or higher reduction in faecal incontinence episodes at 6 months. Health change and quality of life, as measured by the symptom-related quality of life survey (SF-36), improved significantly at 6 months (p=0.016). There were no unanticipated device- or procedure-related adverse events. Mean time to recharge the system was 37 minutes (plus or minus 3 minutes) once or twice per week. All patients were moderately or very satisfied with the system and its effect.

Strengths and limitations

Study involves a small number of people and has a short-term follow up of up to 6 months. The study reports on a single-nonstaged procedure and may not be generalisable to current clinical practice which advises that an external trial phase is done before having a permanent implant.

Pezzella et al. (2021), Benson et al. (2020) and McCrery et al. (2020)

Study size, design and location

Prospective, multicentre, before-and-after study (ARTISAN-SNM study) of 129 people with urinary urgency incontinence (UUI) in whom symptoms were not controlled with or who could not tolerate more conservative treatments. Study done in the US (14 centres), Belgium (1 centre), the Netherlands (2 centres), France (1 centre) and the UK (1 centre).

Of the 129 people in the study, 33% (n=42) had faecal incontinence at baseline (a score of 6 or greater on the Cleveland Clinic Florida-Faecal Incontinence Score [CCF-FIS]. Six-month data from this trial is reported in McCrery et al. (2020), 1-year data in Benson et al. (2020) and 2-year data in Pezzella et al. (2021).

Intervention and comparator

Axonics SNM System, no comparator.

Key outcomes

At 6 months, the average CCF-FIS score in the 41 people with faecal incontinence available at follow up was 4.6 (plus or minus 0.3) compared with 9.3 (plus or minus 0.3) at baseline. For 73% of these people (n=30) the CCF-FIS score was less than 6 at 6 months. At 1 year, the average CCF-FIS score in all people with faecal incontinence reduced from 9.3 (plus or minus 0.5) at baseline to 3.9 (plus or minus 0.6) at 1 year ($p<0.0001$). At 2 years, CCF-FIS was statistically significantly reduced to 3.7 (plus or minus 0.5; p value<0.001). All people in the study were able to recharge their device during the 2-year study. There were no serious device-related adverse events reported.

Strengths and limitations

Multicentre study which included 1 UK centre. This was a non-randomised study, with no comparator or placebo arm. It was not primarily designed to evaluate the efficacy of Axonics SNM system in people with faecal incontinence.

Dudding (2017)

Study size, design and location

Case series involving 5 people with faecal incontinence considered for SNM.

Intervention and comparator(s)

Axonics SNM System, no comparator.

Key outcomes

All patients reported a good response to therapy at 1 month after implantation, defined as over 75% reduction in episodes of faecal incontinence. The St Mark's continence score was reduced from a mean of 18 at baseline to 5 at 1 month. At 3 months, 4 out of 5 patients continued to benefit from therapy. Recharging was done at a median of 7 days (range: 7 to 10 days) with no patient needing greater than 60 minutes per charging session. No patient reported any problems with recharging the device.

Strengths and limitations

This is a UK NHS study. It is a single-site case series involving a small sample of people with no comparator group. The statistical and clinical significance of efficacy outcomes were not reported, and no baseline demographics were available.

Sustainability

The company proposes that the environmental impact of the rechargeable device would be reduced because of less frequent replacement of neurostimulator devices. There is no published evidence supporting this assumption.

Recent and ongoing studies

No ongoing or in-development trials evaluating the use of the technology in the treatment of faecal incontinence were identified.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All of the experts were experienced with sacral neuromodulation (SNM) therapy and 1 out of 4 had used Axonics SNM system before.

Level of innovation

The technology's MRI compatibility and rechargeable battery were identified by the experts as Axonic SNM system's main innovations. However, 1 expert noted that MRI compatibility may be less of an innovation because comparator equipment is now MRI compatible. Three of the experts felt that the rechargeable battery made the Axonics SNM system a minor variation to standard care; 1 of these experts noted that the technology is likely to have equivalent efficacy to the non-rechargeable SNM device currently used as standard care. Three experts noted that a competing technology with MRI compatibility and a rechargeable battery is available but how widely it is used in the NHS was not described.

Potential patient impact

Most of the commentators thought the longer battery life would provide the largest benefit to patients, and that using the new technology would lead to fewer invasive surgeries needed for battery replacement. One expert said that the technology's MRI compatibility would also lead to fewer people needing explanation procedures before having an MRI scan. One commentator said the technology could be thought of as less invasive than standard care but did not believe it would lead to better clinical outcomes overall. Another said that improved clinical outcomes over standard care may only be seen in terms of reduced complications because of the smaller sized implantable pulse generator device.

Three experts said that people needing MRI scans would particularly benefit from the device. Another thought that younger patients would benefit, since the duration of lifetime SNM therapy would be longer compared with older patients. One of the commentators believed that people with a low BMI would also benefit from the technology because of its smaller implant size. People for whom repeated battery changes under anaesthetic would

be unsuitable and people who express a preference for a rechargeable device were also identified by 1 expert as those that would benefit from Axonics SNM therapy.

Potential system impact

Fewer operations and hospital visits for battery replacement and explantations were identified as potential system benefits. Two experts thought that the technology would replace current standard care. Two said it would be an additional option to standard care, with 1 noting that not all patients want a rechargeable device and that one is not always suitable. Two commentators said the technology would cost less than current standard care, while 2 thought it would be cost saving in the long term when battery replacement is considered.

All commentators agreed that there would be no need for facility or infrastructure changes to adopt this technology. Product-specific training for people having therapy and staff involved in their care was identified by 1 expert but this was thought to be minimal. Two experts noted that familiarisation with Axonics SNM system equipment (including programming) would be needed by healthcare professionals, but the basic principles of surgery and the procedure are the same as those used in standard care. The remaining expert did not believe specific training would be needed.

General comments

None of the experts were aware of any potential barriers to adoption. The need for long-term follow-up data was identified by 1 expert and 2 others said that head-to-head comparison data of Axonics and the non-rechargeable SNM device currently used as standard care would be helpful.

Expert commentators

The following clinicians contributed to this briefing:

- Anil Bagul, consultant, locum consultant colorectal and functional bowel surgery, University Hospitals Birmingham NHS Foundation Trust, did not declare any interests.
- Keith Chapple, consultant colorectal and general surgeon, Sheffield Teaching Hospitals NHS Foundation Trust, did not declare any interests.

- Dermot Burke, associate professor of clinical surgery, St James's Hospital, Leeds, did not declare any interests.
- Amir Darakhshan, consultant colorectal and general surgeon, Guy's and St Thomas' Hospital NHS Foundation Trust, did not declare any interests.

Development of this briefing

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