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ORIGINAL ARTICLE

One-stage implant in sacral neuromodulation for faecal incontinence – short-term outcome from a prospective study

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Abstract

Aim: Sacral neuromodulation (SNM) is approved for the treatment of faecal incontinence (FI) in a two-stage technique. With standardized implantation, approximately 90% of patients undergo successful Stage I operation and proceed to a permanent implant (Stage II). The aim of this work was to explore the feasibility of SNM as a one-stage procedure and report the 24-week efficacy.

Method: This study included patients diagnosed with idiopathic FI or FI due to an external anal sphincter defect ≤160° and one or more episodes of FI per week despite maximal conservative therapy. Patients were offered a one-stage procedure if a motor response of the external anal sphincter was achieved in three or more poles with at least one at ≤1.5 mA at lead placement. Patients were followed for 24 weeks. Their evaluation included the Wexner/St Mark's Incontinence Score, Faecal Incontinence Quality of Life score (FIQoL), a visual analogue scale (VAS) for assessing patient satisfaction and a bowel habit diary.

Results: Seventy-three patients with a median age of 60 years (interquartile range 50–69 years) completed this prospective study. Episodes of FI were significantly reduced at the 24-week follow-up, from 13 (8–23) at baseline to 2 (0–5) (p-value = 0002). A ≥50% reduction in the number of FI episodes was achieved in 92% of participants. The Wexner score improved significantly from 16 (14–17) at baseline to 9 (5–13) (p-value < 0.001), and the St Mark's score improved significantly from 18 (16–20) to 11 (7–16) (p-value < 0.001). All domains in the FIQoL score and VAS for patient satisfaction improved significantly following the one-stage procedure.

Conclusion: A one-stage implantation procedure is feasible in selected patients with FI, significantly improving continence, quality of life and patient satisfaction after 24 weeks of follow-up.

KEYWORDS
faecal incontinence, functional outcome, quality of life, sacral neuromodulation

INTRODUCTION

Sacral neuromodulation (SNM) was introduced as a treatment for faecal incontinence (FI) in 1995 [1]. SNM has now become an established treatment option for FI [2, 3] when incontinence does not improve satisfactorily following conservative treatments such as fibre supplements, antidiarrhoeal medications, pelvic floor muscle training or transanal irrigation [4–6].

SNM is currently approved as a two-stage procedure. The first stage (Stage I) involves operative placement of a temporary or permanent stimulation lead(s) that is externalized and tested for 2–3 weeks with an extracorporeal pacemaker to assess treatment outcome before permanent implantation (Stage II). Patients who respond to Stage I with a ≥50% reduction in incontinence episodes or number of days affected by incontinence are considered candidates for Stage II. Stage-II is the implantation of a permanent pacemaker or full implantation of a permanent lead and a pacemaker if a temporary lead is used in Stage I.

Following implementation of the standardized implantation technique [7], approximately 90% of patients experience a successful Stage I test (≥50% symptom reduction) and are offered to proceed to Stage II [8]. With a conversion rate from Stage I to Stage II approaching 90% the staged procedure rationale could be questioned in selected patients. The possibility of a one-stage implantation would hold great value for patients fulfilling specified pre- and perioperative criteria (Table 1). First, the patient burden would be reduced, with fewer restrictions related to the external system (Stage I). Second, the potential risk of implant infection may be reduced with a one-stage implantation. Third, a one-stage implantation would simplify patient flow in the hospital with only one operation schedule compared with the conventional two-stage procedure.

To the best of our knowledge there has been no large multicentre study evaluation of a one-stage implant in patients suffering with FI.

This prospective study aimed to evaluate, in a one-stage setting, the proportion of patients achieving a ≥50% reduction in incontinence episodes 24 weeks postoperatively. Additionally, the study aimed to document the efficacy, including quality of life and patient satisfaction, associated with a one-stage procedure.

What does this paper add to the literature?

This paper is the first to demonstrate that a one-stage implant in sacral neuromodulation is feasible for selected patients suffering from faecal incontinence. Efficacy and patient satisfaction 24 weeks after one-stage implantation are high and comparable to those of the conventional two-stage procedure.

TABLE 1 Pre and perioperative inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Preoperative criteria	Diabetes type II – with complications
One or more FI episode per week	Diabetes type I
Failed conservative therapy	Neurological disorder
Idiopathic FI or external anal sphincter defects ≤160°	Spinal cord injury
Perioperative criteria	Anorectal surgery besides primary obstetric sphincter repair
Implantation according to the 'standardized electrode placement technique'	Pelvic irradiation
Three or more poles of the quadripolar lead with a motor response	Thyroid disease
Motor threshold ≤1.5 mA on at least one pole	Pregnancy
	Congenital anorectal malformation

Abbreviation: FI, faecal incontinence.

METHOD

Patients were recruited from the Aarhus University Hospital and Hvidovre University Hospital, Denmark and the University Hospital of North Norway, Tromsoe, Norway. All three centres are tertiary referral centres for treatment of FI and are regarded as high-volume SNM centres with more than 15 years of experience.

Study inclusion started in November 2016 and ended in November 2019. All patients diagnosed with idiopathic FI or FI due to an external anal sphincter defect ≤160° were eligible if they experienced at least one episode of FI weekly after maximal conservative therapy. Table 1 presents the study inclusion and exclusion criteria.

All patients included in the study were informed that a one-stage implantation was off-label and that the final decision concerning a one-stage implantation was made intraoperatively only if specific perioperative criteria were met. These criteria were a motor response (contraction) of the external anal sphincter in three or more poles and at least one pole with a motor threshold of ≤1.5 mA and implantation according to the 'standardized electrode placement technique' [7] (Table 1). If the above criteria were met, the patient underwent full implantation (one-stage implantation) of a permanent lead (quadripolar foramen lead; quadripolar lead for electrical stimulation® model 3889, Medtronic, Minneapolis, MN) and a pacemaker (InterStim-II®, Medtronic, Minneapolis, MN). Patients who did not fulfil the perioperative stimulation response criteria were excluded from the study and a Stage I procedure was performed. All implantations were performed under general anaesthesia or deep sedation to evaluate the motor response during lead placement. All patients received preoperative intravenous prophylactic antibiotics [1000 mg metronidazole (Aarhus/Hvidovre), 1500 mg cefuroxime (Aarhus/Hvidovre/Tromsoe) and 1000 mg dicloxacillin (Aarhus)] and postoperative oral antibiotics for 4 days [Bioclavid (amoxicillin + clavulanacid) 500 mg × 2; Aarhus].

Patients had the neurostimulator programmed in the outpatient clinic on postoperative day one. As part of another study, patients were randomized between different stimulation amplitudes

during the first 12 weeks of stimulation. For the next 12 weeks (weeks 13–24) all patients were stimulated at the sensory threshold. Subsequently, patients were followed up according to each centre's best practice. The results of the randomized part of the study will be presented in another paper. Information on the randomization procedure/study is available at ClinicalTrials.gov (NCT03261622).

At baseline and after 24 weeks all patients were requested to fill in a 3-week bowel habit diary and answer a collection of questionnaires consisting of the Wexner Incontinence Score [9], the St Marks Incontinence Score [10] and the Rockwood Faecal Incontinence Quality of Life score (FIQoL) [11, 12]. Furthermore, overall satisfaction with bowel function, social function and quality of life was assessed using a numerical visual analogue scale (VAS) range 0–100, where 100 indicates excellent function and 0 indicates poor function [13].

Statistical analysis

A sample size calculation (based on a noninferiority study design) for this study was conducted based on the available literature. Approximately 90% of patients who undergo a Stage I implant will proceed to Stage II. Of these patients, approximately 80% will have a sustained efficacy. On an intention-to-treat basis, 72% of patients offered SNM will have sustained efficacy (≥50% improvement in continence) after 6 months. We expected that 85% of patients offered a one-stage implant would experience a ≥50% improvement in continence. With a power of 90%, a significance level of 5% and a noninferiority limit of 9%, 60 patients should be included. To account for dropout and possible infection leading to explantation 75 patients should be included. A control group was not included as we refer to the available literature. A maximum of 30 patients were included in each department to ensure an even distribution. The data are presented as median and interquartile range (IQR). The Wilcoxon signed-rank test was used to compare results obtained upon initiation of this study with follow-up after 24 weeks. Stata version 10.1 (Stata Corporation, 4905 Lakeway Drive, TX 77846, USA) was used for all statistical analyses.

Ethics

The study protocol was approved by the Regional Committee on Biomedical Research Ethics, Denmark and the Patient Protection Representative Norway (SJO125) and it was registered at ClinicalTrials.gov (NCT03261622). Medtronic was informed of the study but was not involved in the planning, completion or reporting of the study. In case of unexpected adverse events related to the study, patients were protected by national healthcare insurance.

RESULTS

Eighty-five patients were approached of whom 76 (72 women) gave written consent to participate. Three patients were excluded during the trial: one developed a deep infection on the fourth day after implantation and the pacemaker and electrode were therefore explanted. Two patients withdrew consent to participate before the study began.

Seventy-three patients (70 women) with a median age of 60 years (IQR 50–69 years) completed the trial and their results are presented. The median body mass index was 26.3 kg/m^2 (23.5–29.8 kg/m^2). Of the 70 women included, 64 had given birth to a median of 2 (2–3) children. The aetiology was idiopathic in 35 patients and obstetric anal sphincter injury in 38 patients, of whom 23 (61%) had previously undergone primary sphincter repair. At baseline, before SNM, an external anal sphincter defect was observed on ultrasound in 19 patients with a median 90° (50°–120°) defect. All patients had failed to achieve a satisfactory treatment outcome with conservative therapy. Psyllium was tested by 99%, biofeedback by 89%, loperamide by 88% and transanal irrigation was offered to 55% of the patients. The median number of conservative therapies tested was 3 (3–4). Twenty-nine patients were implanted in Tromsoe, Norway, 26 patients in Aarhus, Denmark and 18 patients in Hvidovre, Denmark.

Implantation data

The perioperative inclusion criterion of motor threshold in three or more poles and at least one pole of the quadripolar leads with a motor threshold of ≤1.5 mA was achieved in all 73 eligible patients. In 63 (86%) patients a motor response was achieved in all four poles of the quadripolar lead. The median motor threshold was 1 mA (0.5–1.5 mA) for all poles combined. For the poles separately, the motor threshold was: pole #0, 1 mA (0.5–1.6 mA); pole #1, 1 mA (0.5–1.5 mA); pole #2, 0.53 mA (0.5–1 mA); pole #3, 1 mA (0.6–2 mA). The stimulation threshold needed to elicit a motor response was significantly lower for pole #2 than for pole #1 (p-value = 0.002) and 3 (p-value = 0.0004). The median sensory threshold at the initial programming the day after surgery was 0.55 V (0.4–0.8 V).

Functional results after one-stage implantation

A ≥50% reduction in FI episodes compared with baseline was evident in 67 (92%) patients. The number of FI episodes per 3 weeks was significantly reduced from a baseline median of 13 (8–23) to 2 (0–5) (p-value < 0.001) at the 24-week follow-up. The improvement was equivalent to a median reduction of 88% (75%–100%) in FI episodes. In 24 (33%) patients no FI episodes were registered at the 24-week follow-up.

The St Mark's Incontinence Score was significantly reduced from 18 (16–20) at baseline to 11 (7–16) at the 24-week follow-up (p-value < 0.001). A similar reduction from 16 (14–17) at baseline to 9 (5–13) at the 24-week follow-up (p-value < 0.001) was observed in the Wexner Incontinence Score.

TABLE 2 Rockwood Faecal Incontinence Quality of Life score (FIQoL) and self-reported patient satisfaction at baseline compared with the 24-week follow-up.

	Baseline	Follow-up (24 weeks)	*p*-value
FIQoL			
Lifestyle	2.15 (1.6–2.7)	3.22 (2.5–3.8)	<0.001
Coping/behaviour	1.33 (1.11–1-67)	2.33 (1.63–3.11)	<0.001
Depression/self-perception	2.22 (1.81–2.33)	3.17 (2.51–3.6)	<0.001
Embarrassment	1.67 (1.33–2.33)	2.67 (2–3.67)	<0.001
Patient-reported satisfaction			
Social function	50 (17.5–50)	90 (50–100)	<0.001
Bowel function	20 (10–40)	80 (50–90)	<0.001
Quality of life	45 (15–60)	85 (60–95)	<0.001

Values are Median (IQR)

Quality of life results after one-stage implantation

A highly statistically significant improvement was observed across all subdomains of the FIQoL score at the 24-week follow-up after one-stage implantation (Table 2). Patient self-reported satisfaction (VAS) with social function, bowel function and quality of life all showed a statistically significant improvement after the intervention compared with baseline (Table 2). At the end of the study, three patients decided to discontinue therapy, including one patient who experienced >50% reduction in incontinence episodes but quoted the result as unsatisfactory. All three patients were offered a stoma.

Adverse events

During follow-up, one patient had the whole system explanted due to infection, which is equivalent to an infection rate of 1%. The most common adverse event was pain/discomfort at the pacemaker site, reported by 10 (14%) patients. Furthermore, constipation (one patient), urinary retention (one patient), pelvic pain (one patient) and leg pain (one patient) were reported as adverse events.

Pacemaker settings at the 24-week follow-up

At the 24-week follow-up, the median stimulation amplitude was 0.55 V (0.4–1.05 V).

A monopolar stimulation setting was used in 33 patients and a bipolar one in 40 patients. The median stimulation amplitude applied in patients with monopolar stimulation was 0.45 V (0.35–0.65 V), which was significantly reduced compared with patients stimulated with bipolar setting 0.6 V (0.5–1.25 V) (p-value < 0.001).

DISCUSSION

To the best of our knowledge, this prospective international multicentre observational study is the first to document the feasibility and effectiveness of SNM as a one-stage procedure is treating FI.

SNM is currently approved as a two-stage (Stages I and II) procedure. In many countries, reimbursement is granted for Stage II only if a successful Stage I procedure has been documented. Patients offered initial testing with temporary lead(s), referred to in the literature as a percutaneous nerve evaluation (PNE) test, may proceed to full implant (permanent lead and pacemaker) if they achieve a reduction of 50% or more in FI episodes or days affected by incontinence. However, this cannot be referred to a one-stage implantation as these patients have had a prior PNE test before receiving the final full implant. Although a one-stage implantation without a prior PNE test is considered off-label, this approach holds numerous advantages for both patients and healthcare providers.

The primary endpoint, the number of patients achieving a ≥50% reduction in FI episodes at the 24-week follow-up, was achieved in 92% of the patients. The number of patients achieving this endpoint in the present trial was comparable to or even higher than those previously reported for a conventional two-stage procedure [8, 14, 15]. This higher success rate is probably due to the patient selection and the requirements of optimal perioperative settings (Table 1) to proceed to a one-stage implantation. The improvements in quality of life, patient satisfaction and adverse events were comparable to those obtained with the conventional two-stage procedure [15, 16]. Patients included in the present trial had more clinical contact than our regular patients. As they were concurrently involved in another trial, they were seen postoperatively after 8 and 12 weeks, deviating from the standard practice. This extra attention could theoretically lead to a placebo effect, as described in a randomized study by Knowles et al. [17]. However, we do not anticipate that two extra visits would influence our clinical results significantly.

In 2017, the 'standardized implantation method' was published, providing guidance for optimal lead placement without any clinical evidence to support its use [7]. However, the 'standardized implantation method' has now been documented to result in more active electrode poles of the permanent lead at a reduced stimulation amplitude, improved functional outcome and reduced need for reprogramming [18–20]. Given the new evidence supporting the 'standardized implantation method', it can be expected that the success rate for the Stage I will surpass the previously reported 90% success rate [8, 15]. Given these high success rate of Stage I, defined

by a ≥50% reduction in FI episodes as a success criterion, one might question the need for the current staged procedure for SNM.

In 2020, Lee et al. published a retrospective study of 15 patients undergoing one-stage SNM for overactive bladder or urinary retention and found the therapy effective (≥50% improvement) in 93.3% of the patients [21], although they did not fully describe the rationale for offering some patients a one-stage procedure.

In the present study, we included patients expected to be optimal candidates for SNM based on our clinical experience (Table 1). Furthermore, an optimally placed lead was needed before the one-stage procedure was considered (Table 1). A lead was considered optimally placed in patients if three electrode poles were active and one pole with a motor threshold ≤1.5 mA was present. The perioperative criteria were fulfilled in all patients included in the present trial. Four active electrode poles of the quadripolar lead were achieved in 86% of the study participants. The high number of active poles and the low motor threshold indicate that the lead has been placed close and parallel to the target nerve. This explains the low sensory threshold recorded at the first programming [0.55 V (0.4–0.8 V)] and the therapeutic stimulation threshold at the 24-week follow-up [0.55 V (0.4–1.05 V], both of which are much lower than those previously reported [19]. All implant placements were performed by colorectal surgeons with more than 15 years of experience in performing SNM. The 'standardized electrode placement technique' had been implemented in all centres years before its publication in 2017.

A one-stage implantation procedure holds several advantages for patients. The potential risk of deep infections leading to explantation of the lead and pacemaker was reported to be 1.96% in a large retrospective study of 1930 patients [22]. In the present study, one (1%) patient developed an infection leading to explantation. In theory, the infection rate may be reduced because patients will undergo only one surgical procedure and because the infection risk associated with use of an externalized extension wire is avoided. Due to the small number of infections and the limited number of patients in the present study, no firm conclusion can be drawn regarding the risk of infection. Morbidity and discomfort may be reduced for patients as they can have a full implant in one procedure. Patients may spend less time in the hospital; consequently only one recovery period will be needed, reducing patients' time away from work and daily activities. Furthermore, a clear advantage of opting for a one-stage implantation procedure is the avoidance of the inconvenience associated with restricted bathing and dressing maintenance typically required during the testing phase (Stage 1). In addition, the healthcare system stands to gain from diminished utilisation of operation capacity, requiring only one operation slot.

A one-stage procedure has been found to be cost-effective for urological indications. To the best of our knowledge, no cost-effectiveness analysis of one-stage implantation for FI has so far been conducted. Based on the urological literature, a success rate of 61.3%–71% (≥50% improvement) in patients following a one-stage implantation is considered cost effective [21, 23, 24]. A cost-effectiveness analysis must be based on national cost and reimbursement rates and may not be directly transferable to the colorectal field and to the national level.

The timeframe of this study was extended due to the global coronavirus disease pandemic, and our ethical approval allowed us to follow the patients only for 24 weeks. Further research with longer follow-up of patients offered one-stage SNM is needed to clarify the role of loss of efficacy over time.

CONCLUSION

SNM as a one-stage procedure is feasible and effective in selected patients with FI. Compared with the conventional two-stage procedure, a one-stage procedure improves continence, quality of life and patient satisfaction equally without any associated increase in the number of adverse events. Approval of one-stage implantation for patients fulfilling specific pre and perioperative criteria (Table 1) could reduce the patient burden and healthcare costs.

AUTHOR CONTRIBUTIONS

Jakob Duelund-Jakobsen: Conceptualization; investigation; writing – original draft; formal analysis; methodology; validation; project administration; supervision; funding acquisition; data curation; visualization; software. **Steen Buntzen:** Conceptualization; investigation; writing – review and editing; methodology; project administration; supervision; validation; data curation; funding acquisition. **Lilli Lundby:** Conceptualization; investigation; methodology; validation; writing – review and editing; project administration; supervision; data curation; funding acquisition. **Søren Laurberg:** Conceptualization; investigation; funding acquisition; writing – review and editing; validation; methodology; project administration; supervision; data curation. **Michael Sørensen:** Conceptualization; investigation; methodology; validation; writing – review and editing; project administration; supervision; data curation. **Mona Birgitte Rydningen:** Conceptualization; investigation; methodology; validation; writing – review and editing; project administration; supervision; data curation.

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CONFLICT OF INTEREST STATEMENT

All authors have received honoraria from Medtronic as speakers at meetings and/or as a member of the medical advisory board. The study, design, performance, analysis and reporting have been conducted without the influence of Medtronic.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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