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Retrospective Study

- 32 Outcomes and efficacy of magnetic resonance imaging-compatible sacral nerve stimulator for management of fecal incontinence: A multi-institutional study

Katuwal B, Thorsen A, Kochar K, Bhullar R, King R, Drelichman ER, Mittal VK, Bhullar JS

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Editorial Board Member of *World Journal of Radiology*, Gang-Hua Tang, MD, PhD, Professor, Chief, GDMPA Key Laboratory for Quality Control and Evaluation of Radiopharmaceuticals, Nanfang Hospital, Southern Medical University, Guangzhou 510515, Guangdong Province, China. gtang0224@126.com

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Retrospective Study

Outcomes and efficacy of magnetic resonance imaging-compatible sacral nerve stimulator for management of fecal incontinence: A multi-institutional study

Binith Katuwal, Amy Thorsen, Kunal Kochar, Ryba Bhullar, Ray King, Ernesto Raul Drelichman, Vijay K Mittal, Jasneet Singh Bhullar

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Binith Katuwal, Department of Surgery, Ascension Providence Hospital, Michigan State University College of Human Medicine, Southfield, MI 48075, United States

Amy Thorsen, Department of Colon and Rectal surgery, Alina Health Abbott Northwestern Hospital, Minneapolis, MN 55407, United States

Kunal Kochar, Colon and Rectal Surgery, Advocate Illinois Masonic, Park Ridge, IL 60068, United States

Ryba Bhullar, Volunteer Student, Department of Research, Ascension Providence Hospital, Southfield, MI 48075, United States

Ray King, Colon and Rectal Surgery, University of Wisconsin, Madison, WI 53715, United States

Ernesto Raul Drelichman, Jasneet Singh Bhullar, General and Colorectal Surgery, Ascension Providence Hospital, Michigan State University College of Human Medicine, Southfield, MI 48075, United States

Vijay K Mittal, Department of Surgery, Department of Medical Education, Ascension Providence Hospital, Michigan State University College of Human Medicine, Southfield, MI 48075, United States

Corresponding author: Jasneet Singh Bhullar, FACS, FASCRS, Doctor, Staff Physician, Department of General and Colorectal surgery, Ascension Providence Hospital, Michigan State University College of Human Medicine, Southfield, MI 48075, United States.

drjsbhullar@gmail.com

Abstract

BACKGROUND

Fecal incontinence (FI) is an involuntary passage of fecal matter which can have a significant impact on a patient's quality of life. Many modalities of treatment exist for FI. Sacral nerve stimulation is a well-established treatment for FI. Given the increased need of magnetic resonance imaging (MRI) for diagnostics, the InterStim which was previously used in sacral nerve stimulation was limited by

MRI incompatibility. Medtronic MRI-compatible InterStim was approved by the United States Food and Drug Administration in August 2020 and has been widely used.

AIM

To evaluate the efficacy, outcomes and complications of the MRI-compatible InterStim.

METHODS

Data of patients who underwent MRI-compatible Medtronic InterStim placement at UPMC Williamsport, University of Minnesota, Advocate Lutheran General Hospital, and University of Wisconsin-Madison was pooled and analyzed. Patient demographics, clinical features, surgical techniques, complications, and outcomes were analyzed. Strengthening the Reporting of Observational studies in Epidemiology (STROBE) cross-sectional reporting guidelines were used.

RESULTS

Seventy-three patients had the InterStim implanted. The mean age was 63.29 ± 12.2 years. Fifty-seven (78.1%) patients were females and forty-two (57.5%) patients had diabetes. In addition to incontinence, overlapping symptoms included diarrhea (23.3%), fecal urgency (58.9%), and urinary incontinence (28.8%). Fifteen (20.5%) patients underwent Peripheral Nerve Evaluation before proceeding to definite implant placement. Thirty-two (43.8%) patients underwent rechargeable InterStim placement. Three (4.1%) patients needed removal of the implant. Migration of the external lead connection was observed in 7 (9.6%) patients after the stage I procedure. The explanation for one patient was due to infection. Seven (9.6%) patients had other complications like nerve pain, hematoma, infection, lead fracture, and bleeding. The mean follow-up was 6.62 ± 3.5 mo. Sixty-eight (93.2%) patients reported significant improvement of symptoms on follow-up evaluation.

CONCLUSION

This study shows promising results with significant symptom improvement, good efficacy and good patient outcomes with low complication rates while using MRI compatible InterStim for FI. Further long-term follow-up and future studies with a larger patient population is recommended.

Key Words: Fecal incontinence; Sacral nerve stimulation; InterStim; Magnetic resonance imaging; Sacral neuromodulation

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Core Tip: The advent of newer technology has improved the outcome of various diseases including FI. However, not all patients were able to get full access to this technology in part because of lack of adequate technology available. Moreover, the patients had to endure unwanted surgeries, especially ex-plantation of the stimulators in case magnetic resonance imaging (MRI) was needed. The introduction of a safe MRI-compatible sacral nerve stimulator has solved this problem. The MRI-compatibility is noted to be safe in specific MRI settings. The patients are benefited and the technology seems to be similar to the previous technology available, however with this added benefit.

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INTRODUCTION

Fecal incontinence (FI) is an involuntary passage of feces or gas for at least a month duration in an individual who previously had control[1]. FI is relatively common and is an extremely debilitating condition affecting many individuals. The prevalence of the condition has been reported to be 1.6% to 15% depending upon age, sex and medical comorbidities. The majority of the cases are found in females and in institutionalized populations[2]. A United States-based study has shown prevalence of 8.3% in the non-institutionalized population[3], the incidence rising to almost 50% in institutionalized populations[4]. The condition can be a cause of extreme physical and emotional stress, and the psychosocial stigma associated with the condition might be the cause of why so many patients do not seek early medical care[5].

FI can have many causes ranging from abnormalities in the pelvic floor muscles, rectal or anal sphincters to impairment of the function of the spinal cord, central nervous system or the autonomic nervous system[6]. FI is mostly managed conservatively with dietary modification, medications like loperamide or cholestyramine to control the diarrheal symptoms, and sometimes biofeedback[7]. Surgical options include sphincteroplasty or repair of the damaged sphincters, injection of bulking agents into the anorectal mucosa, neo sphincter placement, neuromodulation, and in the

extreme of cases, fecal diversion with a colostomy[7].

Sacral neuromodulation, commonly termed sacral nerve stimulation has emerged as a treatment option for patients with FI. Sacral nerve stimulation is a second-line treatment in patients with FI when other conservative measures including fiber supplementation, biofeedback, and others fail to control the symptoms. It was initially developed as a treatment for urinary incontinence, specifically urge incontinence, by Tanagho and Schmidt in 1981[8]. Following promising results, it was introduced for the treatment of fecal incontinence by Matzel and group who published their results in 1995[9]. The modality of treatment for FI was approved by the United States Food and Drug Administration (FDA) in 2011. Since its introduction, it has been widely used in the United States and all around the world for the treatment of FI with excellent outcomes. The benefits and sustained effects shown by this therapy have even substantiated it as a primary surgical treatment modality in most patients[10,11].

During the initial phases of this treatment, the tined leads that were used as a part of the device were not compatible with the magnetic resonance imaging (MRI) machines thus limiting its use in those populations who needed an MRI. MRI done in these patient groups has caused unwanted effects like heating and tissue damage, pain, shock, lead breakage, and permanent damage of the neurostimulator[12,13]. In those patient groups, either the sacral neuromodulation (SNM) treatment was not offered or lead removal was done in case MRI was needed. Approximately 15%-18% of SNM-implanted patients have required an explantation of the device for a variety of reasons, one being patients requiring MRI [14-17]. One study showed that almost 23% of total removals were attributed to patients requiring MRI[18]. Given the increasing use of MRI for diagnostic purposes, there was a strong need for the development of MRI-compatible tined lead. Subsequently, the MRI-compatible leads were developed by two companies, Axonic and Medtronic. They were recently approved by the Food and Drug Administration in 2019 and 2020 respectively and have been brought in to clinical use[19,20].

This multicentric study was aimed to evaluate the findings of the earliest use of MRI-compatible neuromodulator systems in the treatment of fecal incontinence.

MATERIALS AND METHODS

The study was a retrospective, multi-institutional analysis from 5 different centers utilizing the MRI-compatible InterStim™ sacral nerve stimulator in the treatment of fecal incontinence. Data of patients who underwent MRI-compatible Medtronic InterStim™ (Minneapolis, United States) placement at UPMC Williamsport, University of Minnesota, Advocate Lutheran General Hospital, University of Wisconsin-Madison, and Providence Hospital was pooled and analyzed.

Procedure

All the patients with fecal incontinence in the study underwent the sacral nerve stimulation procedure as a staged procedure. The procedure consisted of a testing phase which included either peripheral nerve stimulation (PNE) or stage I tined lead placement. Following the successful testing phase, the patients underwent a permanent lead placement as a stage 2 procedure along with the impulse generator.

PNE: In peripheral nerve evaluation, the patient is placed in a prone position, and anatomic landmarks are used to help localize the S3 sacral nerve foramen. A needle is passed through the S3 sacral foramen and confirmed to be in the appropriate position if sensory responses are elicited by stimulating the needle. Under local anesthesia, a tingling or tapping sensation should be felt preferably within the perineal region. The temporary leads are left in place for 7 to 10 d and then easily removed. This stage can be done in the office under local anesthesia.

Stage 1 tined lead placement: This stage involves the placement of a permanent tined lead (with four electrodes) using anatomic landmarks and fluoroscopy. The lead is temporarily hooked up to an external power supply. Flexion of big toe and bellowing of the anal opening is seen with stimulation of the S3 nerves. This test stage offers a longer trial period of 2 wk as opposed to 1 wk with a PNE. This procedure can be performed under intravenous sedation or general anesthesia.

Stage 2 permanent implantation of SNS device: After successful PNE or stage 1, this stage involves placement of the permanent lead along with a subcutaneously placed impulse generator.

Not all patients required PNE. Some patients underwent stage 1 Lead placement without the need for PNE. This was primarily by the surgeon's discretion. Patients who underwent PNE underwent stage 2 without the need for stage 1. Sometimes, patients with an equivocal PNE require a stage 1 implant placement, however, this did not happen in our patient cohort.

Approval from the institutional review board was attained for the study. Patient demographics, clinical features, surgical technique, complications, and outcomes were analyzed. All patients had a defecation diary which was maintained pre and post-treatment. Wexner incontinence scores were evaluated in the pretreatment and the post-treatment phase to evaluate the effectiveness of the treatment[21]. Percentages were identified for categorical data and the mean was calculated for continuous data. Data compilation and analysis was done using Statistical Package for the Social Sciences (SPSS) Version 20. The manuscript was completed following STROBE cross-sectional reporting guidelines[22].

RESULTS

A total of 73 patients underwent the implantation of the MRI-compatible InterStim™. The mean age of patients was 63.29

± 12.2 years. Fifty-seven (78.1%) patients were females and forty-two (57.5%) patients had diabetes. All patients had bothersome fecal incontinence and had failed conservative management including fiber supplementation and biofeedback at which point they were offered sacral neuromodulation. In addition to incontinence, other overlapping symptoms included diarrhea (23.3%), fecal urgency (58.9%), and concomitant urinary incontinence (28.8%) (Table 1). Fifteen (20.5%) patients underwent PNE before proceeding to a definite implant placement. Thirty-two (43.8%) underwent rechargeable InterStim™ placement (Table 2). Complications of lead migration during the procedure were seen in 7 patients and subsequently, a slight adjustment in the procedural step was done in 10 cases by one surgeon, which included suturing the lead to the subcutaneous tissue. Complications were seen in 7 (9.6%) patients which included nerve pain, hematoma, infection, lead fracture, and bleeding (Table 3). 3 (4.1%) had their implants removed (Table 4). One patient required explantation due to infection, the others were for lead fracture and no improvement in symptoms. The mean follow-up was 6.62 ± 3.5 mo (mean ± SD). Sixty-eight (93.2%) patients reported significant improvement of symptoms on follow-up evaluation (Table 1 and Figure 1).

DISCUSSION

Since the introduction of sacral nerve stimulation, this modality has been increasingly used for the treatment of fecal incontinence. Multiple studies across multiple countries have consistently shown its long-term efficacy in the management of FI [10,11]. There was a long-term study done at the University of Minnesota where the previously available InterStim system was evaluated. This study was done on 133 patients with a mean age of 60.5 years with a mean duration of incontinence symptoms of 7 years. The mean length of follow-up in this study was 3.1 years with 83% completing all or part of the 3 years follow-up assessment. At 3 years follow-up, 86% of patients reported improvement in symptoms of incontinence > 50%. The common adverse events related to the device and therapy were pain (28%), paresthesia (15%), change in sensation of stimulation (12%) and infection (10%) [10]. This is almost comparable to the current study done in multi-institutional data on the MRI-compatible system, albeit in the short term. Our study did show that the MRI-compatible system is at least in the short term comparable to the previously available system.

There were other studies with the previously available InterStim system as well. A similar study from Hull *et al* [11] showed an 89% sustained effect at 5 years showing clear effectiveness of sacral neuromodulation in the treatment of fecal incontinence. A systematic review on sacral nerve stimulation for FI analyzing six previous studies also showed an improvement in continence in a proportion of patients with fecal incontinence [23]. With increased utilization of the MRI for diagnostics, a need for an MRI-safe technology was warranted. Previously available InterStim I and II systems were conditionally MRI-compatible. These available leads were not recommended to be used with MRI below the head or for full-body scanning [24]. The availability of the MRI-compatible InterStim has provided a newer dimension to the treatment of fecal incontinence and provided hope to so many patients in whom the therapy was not possible a few years ago.

Adverse events such as device malfunction, unintended stimulation, and thermal burns have been reported when the patients were scanned with the implanted devices that were available previously [12]. All the adverse events can have a negative impact on patient care and health care delivery. Device malfunction or damage might lead to loss of therapy and ultimately need for device replacement or explantation, adding the burden on patients and the healthcare system. Unintended stimulation can occur by induced current release from the electrode, which can cause discomfort or even pain [12]. The most worrisome adverse effect is the heating of the electrodes with an increased risk of thermal burns. With all these reported adverse events, MRI scans therefore were not recommended in the presence of these SNS devices when performed below the head [24].

Although smaller off-label MRI scanning outside of the manufacturer's recommendations for the previously available InterStim systems have been done with careful precautions showing no adverse effects, these studies should be very carefully interpreted [25-27]. Generalized conclusions about MRI safety based upon these studies with off-label use would be very dangerous and is not recommended [28].

With increased research and rigorous testing, Medtronic introduced the InterStim Micro and SureScan leads which was approved by the FDA in 2020. These systems were MRI-compatible in certain conditions.

Table 5 shows the key parameters for full-body MRI scans using Medtronic InterStim systems which are MRI-compatible (Table 5) [12].

The introduction of this technology has offered wider flexibility in MRI scanning protocols and is likely going to improve patient access to MRI. It ultimately serves to benefit the patient population and alleviate burdens in clinical practices.

We did encounter adverse effects with the system which were at least comparable, if not better with the evidence available on the previously available InterStim (Supplementary Table 1). This should be interpreted with caution as our study period is significantly shorter than the previously available studies. Using the newer technology did come with some technical challenges. There was a clear identification of migration of lead which was more frequent than the older InterStim lead because of the miniature size of the lead which required a different technique to place the leads. However, the challenge was overcome by a change in the technique wherein the lead was sutured to the subcutaneous tissue.

Our study comes with clear limitations. The retrospective nature of the study comes with its inherent limitations. This study has only highlighted short-term outcomes and further long-term follow-up and analysis is needed to see if this technology fares similar to its previous counterpart in the long term.

Our study is the first of its kind to evaluate the safety and effectiveness of MRI-compatible InterStim™ devices in clinical practice. Our study has shown that it can safely be used with similar efficacy and similar adverse effects as

Table 1 Baseline characteristics of patient undergoing sacral nerve stimulation using magnetic resonance imaging-compatible InterStim™ system

Variable/Characteristics	Percentage	mean ± SD
Sex as F/M	78.1/18.1	-
Diabetes	57.5	-
Fecal incontinence	98.6	-
Diarrhea	22.1	-
Urinary incontinence	28.8	-
Age in yr	-	63.29 ± 12.2
Follow-up in month	-	6.62 ± 3.5

F: Female; M: Male; SD: Standard deviation.

Table 2 Characteristics of procedures done during sacral nerve stimulation

Intervention performed	Percentage	Remarks
Procedure		
Peripheral nerve evaluation	20.5	-
Stage 1 f/by full implant	76.7	-
Stage 1 only	1.4	Patient did not show good response
Rechargeable InterStim™	43.8	-

Remark: One patient decided to not go ahead with Stage 2 after a PNE.

Table 3 Complications or adverse events related to the InterStim™ placement

Complications/Adverse events	Percentage	Number
Intraoperative lead migration	9.6	7
Infection	1.4	1
Hematoma	1.4	1
Nerve pain	2.8	2
Retained lead/fracture	2.8	2
Did not work	1.4	1

Table 4 Further modification of technique and removal of leads related to the complications

Interventions	Percentage	Number
Change of technique ¹	12.98	10
Removal of leads	4.1	3 ²

¹Suture lead to subcutaneous.

²Infection (n = 1); Lead fracture (n = 1); Did not work (n = 1).

compared to previously available devices. Moreover, the efficacy of the available devices has been shown to be close to other studies at 93.2%. Longer follow-up is needed to assess if beneficial effects are persistent at 3 to 5 years.

Table 5 Parameters for full body magnetic resonance imaging scans in presence of Medtronic InterStim with SureScan leads (Adapted from Huang X *et al*[12])

Scanner strength	1.5T	3T
SAR limit in W/kg	2	1.4
B1 +rms Limit in μ T	4	2
Allowed continuous scan time	30 min	30 min
Wait time	5 min	5 min

Abbreviations: MRI, Magnetic Resonance Imaging; rms, root mean square; SAR, specific absorption rate; T, Tesla

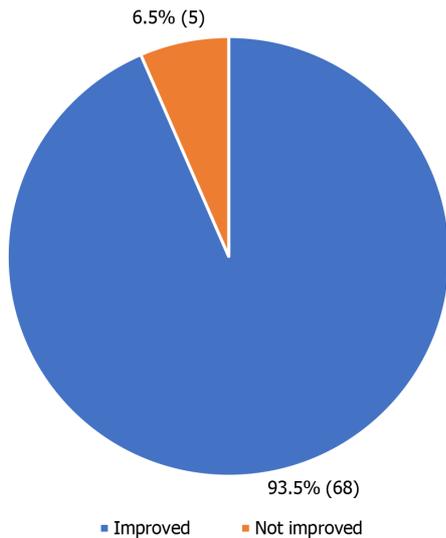


Figure 1 Showing improvement of symptoms at follow-up.

CONCLUSION

This is the first study to evaluate the use and efficacy of MRI-compatible InterStim™ in clinical practice. This study showed that the intervention can be done with no added adverse effects or complications. Although initial studies show that the leads are safe to be used in patients undergoing full-body MRI scans, studies with large sample data will be required in the future to evaluate further.

ARTICLE HIGHLIGHTS

Research background

Fecal incontinence is a disease condition with significant morbidity and social stigmata. Many modalities are used in its treatment and sacral nerve stimulation, lately has been widely accepted as the second line treatment, after the conservative measures fail. Sacral nerve stimulation has been shown to be beneficial in short and long term studies. However, one limitation of its use in the past was concurrent use with magnetic resonance imaging (MRI), which was considered unsafe if used for MRI below the head. Almost 23% of the removals of implants was because the patient required MRI. For this reason, multiple tests and innovation was done and a newer tined lead was developed which was safe to be used with MRI under specific settings. This was United States Food and Drug Administration approved for use in 2020. Our study is to evaluate the efficacy and outcomes of using this recently available treatment modality in fecal incontinence.

Research motivation

Main topics we are trying to deal with are: (1) Does the currently available tined lead (InterStim), which is safe to use in MRI, reciprocate the outcomes and efficacy to the previously available tined lead (InterStim); (2) Any new challenges were faced related to the currently available tined lead. The study is important as this would definitely help us take a leap forward in the management of fecal incontinence. If the outcomes are similar to the previously available system, this will give more confidence to the providers and also will provide benefits to patients.

Research objectives

The objective of this study was to evaluate whether the currently available MRI compatible sacral nerve stimulation system is as efficacious and as safe as the previously available system. At least in the short term, the efficacy is good with a similar safety profile. However, future research including longer follow up results from the current study and future studies with a larger sample size will be needed to further substantiate the findings.

Research methods

This was a retrospective analysis of prospectively collected data from multiple institutions. SPSS 20 was used for data analysis. Descriptive statistics were done including frequencies, percentages, and means were calculated from the data.

Research results

The mean age was 63 years old. There were concomitant symptoms of diarrhea in 23%, fecal urgency in 58.9% and urinary incontinence in 28.5% of the patients. Patients either underwent peripheral nerve stimulation (PNE) or stage 1 as the first procedure followed by stage 2 of implant placement. 15 (20.5%) patients underwent PNE before proceeding to a permanent implant. One important adverse event noted was an external lead connection migration, which was seen in 7 (9.6%) patients after stage 1 procedure. One patient required explantation due to infection, 7 (9.6%) patients had complications which were nerve pain, hematoma, infection, lead fracture and bleeding. Mean follow up was 6.62 months and 93.2% patients reported significant improvement of symptoms. These findings at least in the short term are efficacious and safe as the previously available system, however, long term data and future studies with increased power are needed.

Research conclusions

A new theory that this study proposes is that the newer tined lead (InterStim) for treatment of fecal incontinence is as efficacious and has similar safety profiles as compared to the previously available system.

Research perspectives

The direction of the future research should be towards conducting more high powered studies, including evaluating the newer system with the MRI usage to see whether the safety with the MRI can be substantiated.

FOOTNOTES

Author contributions: Katuwal B, Bhullar JS contributed equally to the design, analysis, and manuscript preparation; Thorsen A, King R, Kochar K, and Drelichman E contributed equally to data acquisition and manuscript writing; Bhullar R, and Mittal V contributed to the manuscript writing and data analysis portion of the study; All authors have read and approved the final manuscript.

Institutional review board statement: The study was exempted by the Institutional Review Board at Providence Hospital. No patient identifiers were used for the data acquisition or analysis.

Informed consent statement: Consent was not needed as the study was retrospective without exposure to the patients' data.

Conflict-of-interest statement: No conflict of interest noted for any authors at the time of the study. This study was presented at the American Society of Colon and Rectal Surgeons Conference held in Tampa, Florida in 2022 and was published as an abstract. This study was also presented at the Fecal Incontinence and Obstructed Defecation Conference in 2022 which was held in Rome, Italy.

Data sharing statement: The dataset was made available from the corresponding author. This was retrospective data, so consent was waived. The presented data are anonymized and risk of identification is low.

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ORCID number: Binit Katuwal 0000-0002-9320-9414; Jasneet Singh Bhullar 0000-0003-2847-7751.

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