First Report of Magnetic Resonance Imaging in Patients with Implanted InterStim Twin (model 7427T) Sacral Nerve Stimulator

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Purpose: To detect possible effects of magnetic resonance imaging (MRI) scans on the function of an InterStim Twin sacral nerve stimulation (SNS) device and on patient's health. There is currently no authorization for MRI scans in InterStim Twin SNS at all.

Material and Methods: 10 patients with Interstim Twin sacral nerve stimulator implants underwent a singular MRI scan. Before the MRI was performed, the SNS device function was evaluated and the device was deactivated by the implanting urologist. Continuous monitoring took place during the MRI procedure. Micturition-time chart pre- and post MRI procedures were conducted. After the MRI session was completed, the implanted device was examined once more and reactivated, function was then re-evaluated.

Results: A total of 10 patients required MRI examinations in 8 different body regions. No patient reported pain or discomfort during and after the MRI scan. After reactivation of the InterStim Twin device following the MRI, impedances and stimulation amplitude, micturition frequency, urgency, and incontinence episodes remained stable. No significant differences between pre- and post MRI were found ($p > 0.05$).

Conclusion: This is the first report of patients successfully undergoing a MRI scan despite a previously implanted Interstim Twin sacral nerve stimulator. No negative effect of SNS function or negative side effects for the patients were observed.

Keywords: magnetic resonance imaging, sacral nerve stimulator, InterStim Twin

INTRODUCTION

Although MRI-safe devices have been introduced recently[1,2] the vast majority of the 300,000 InterStim systems worldwide are not approved for full-body MRI, resulting in the frequent question for off-label MRI examinations in patients with legacy Interstim devices. According to the Neuromodulation MRI Safety Status, MRI scans in patients with sacral nerve stimulation (SNS) are only feasible under strict regulations. So far, there is no authorization for MRI scans in InterStim Twin (model 7427T, Medtronic, Inc) at all[1]. This is due to concerns about dislodgement of the device, unintended stimulations, and, especially, heating of the leads and the device[2,3]. However, increasing numbers of indications for MRI scans require new regulations. It has been estimated that more than 50% of patients with a cardiac pacemaker or neurostimulator will have an MRI indication over their lifetime[4,5]. There have been no reports of MRI scans with InterStim Twin implants so far. An aging population with an increasing number of comorbidities will lead to a growing number of MRI scans in this patient group. The aim of this study was to assess possible impacts of MRI scans on the function of Interstim Twin devices and on patient's safety.

MATERIAL AND METHODS

The data of this retrospective analysis originates in the necessity for MRI diagnostic assessment of various disorders despite implanted SNS devices. Wherever possible, alternative methods other than MRI for diagnosis were utilized. A written informed consent to perform the MRI scan with explicit notice regarding possible risks due to the SNS device was obtained from all patients. MRI was performed as a standard with 1.5 Tesla. Implanted pulse generators were examined before and after MRI procedures. All patients had impedances, battery life, stimulation amplitude and a micturition-time chart including micturition frequency, urgency, and incontinence episodes recorded prior to the MRI scan; then the amplitude of the implanted impulse generator (IPG) was reduced to zero and the IPG was switched off. Patients were monitored continuously during and after the procedure. The implanting urologist was present before, during, and after the MRI scan. He specifically informed and monitored each and every patient himself. A list of questions was utilized, which included unspecific questions such as: "How are you feeling?", as well as specific questions such as: "Do you or did you at any point experience heat or pain in your pelvic region?" After the MRI session, the site of the implanted device was examined to detect potential changes.

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Received & Accepted

Table 1. Number of MRI scans each patient received

Body site	Number of MRI	MRI (mean minutes)
Knee	3	17.7 ± 1.2
Carotisangiography	1	20
Femoralisangiography	1	20
Schoulder	1	18
Cervical cord	2	20.5 ± 0.5
Throracical cord	1	20
Lumbal cord	2	20 ± 0
Central nervous system	1	27
Total 8 regions	Total 12 MRI	Total min 19.9 ± 2.5

Impedances, battery life, and stimulation amplitude were checked once again, devices were then reactivated with their previous setting with the use of the physician programmer (N´Vision, Model 8840). Micturition-time chart was asked via phone approximately one week after the MRI. Differences in stimulation settings and micturition-time chart were calculated with the paired *t*-test.

RESULTS

Between 2005 and 2016, our department implanted the Interstim Twin neurostimulator (InterStim® neurostimulator; Medtronic, Inc, Minneapolis, MN, USA). In the course of those 11 years, 10 patients (8 women, 2 men; age: 56 years – 87 years, mean 73.4 years) with Interstim Twin implants required magnetic resonance imaging in the subsequent years. MRI investigations were conducted with 1.5 Tesla in 8 different regions of the body. As some of the MRI scans were carried out in more than one body region, 10 MRI scan sessions resulted in a total of 12 radiological results. 9 MRI investigations were necessary due to orthopaedic causes, 1 was due to neurological problems and 2 were due to vascular causes. On average, patients were exposed to the magnetic field 19.9 ± 2.5 min. The longest MRI scan was performed on the brain and took 27 minutes (**Table 1**).

During and after the MRI scan, no patient reported any symptoms. All patients negated sensations of heat or discomfort at the implantation site of the electrodes and the IPG. After the implanted sacral nerve stimulator was reactivated following the MRI, impedances pre (1010.1 ± 0.34) and post MRI (1010.3 ± 0.29) showed no significant change ($p = 0.09$), as well as the stimulation amplitude (pre MRI 1.28 ± 0.048, post MRI 1.29 ± 0.047, $p = 0.121$). Micturition frequency (pre MRI 5.31 ± 0.98, post MRI 5.61 ± 1.01, $p = 0.68$), urgency (pre MRI 2.8±0.79, post MRI 2.8±0.85, $p = 0.36$), and incontinence episodes (pre MRI 1.77 ± 0.73, post MRI 1.76 ± 0.41, $p = 0.85$) remained stable. In all tested parameters, no significant differences between pre- and post MRI were found (**Table 2**).

DISCUSSION

Up to now, there is no authorization for MRI scans in patients carrying an Interstim Twin implant, resulting in recommendations to avoid all off-label MRI scans in patients with SNS or explanting and reimplanting the device in patients with the need for an MRI. The basis for this policy is that potential hazards such as heating of the leads and damage to the IPG might occur, resulting in painful stimulation[2,3]. However, MRI is an important diagnostic tool for a variety of diseases, and surgery to remove an important device cannot be justified due to potential complications. So far, studies conducted on patients with other implantable devices, such as pacemakers, have found the examination with MRI at 1,5 Tesla to be safe[5,6]. Nazarian et al. reported on 1509 patients with cardiac devices having off-label MRI scans. No significant adverse events have been reported with 1.5 Tesla[7]. Previous studies have demonstrated no serious adverse outcomes during and after MRI in patients with the Medtronic SNS InterStim and InterStim II of several regions of the body[8,9,10]. This study reports the first series of successful MRI examinations in 10 patients with an Interstim Twin device with no negative effects, neither on the patients nor on the SNS device. However, several limitations of our study should be noted. First, the small patient cohort, this relatively small number is due to the fact that Interstim Twin implants are not very common and that the indications for MRI scans without an alternative method of diagnostic tools are limited also. Second, the data were acquired at a single centre and may not be generalizable to other clinical settings and MRI facilities. Third, in this study cohort only two MRI of the pelvic region were included due to the non-selectivity of patients. Therefore, a study with a larger number of patients, including more patients with pelvic region MRIs should be performed.

CONCLUSIONS

This is the first report of patients successfully undergoing MRI scans despite a legacy, non-full-body MRI compatible Interstim Twin SNS implant. 10 patients underwent MRI with no negative effect on the functional outcome of the SNS device or negative side effects for the patients.

Table 2. Comparison of pre- and post MRI settings

	Amplitude (mA)	Impedance (Ω)	Micturition frequency	Urgency episodes	Incontinence episodes
Pre-MRI1.	28 ± 0.048	1010.1 ± 0.34	5.31 ± 0.98	2.8 ± 0.79	1.77 ± 0.73
Post-MRI	1.29 ± 0.047	1010.3 ± 0.29	5.61 ± 1.01	2.8 ± 0.85	1.76 ± 0.41
P value	$p = 0.12$	$p = 0.09$	$p = 0.68$	$p = 0.36$	$p = 0.85$

REFERENCES

1. Coolen RL, Groen J, Blok B: Electrical stimulation in the treatment of bladder dysfunction: technology update. Med Devices. 2019;12:337-345.
2. Thornton JS: Technical challenges and safety of magnetic resonance imaging with in situ neuromodulation from spine to brain. Eur J Paediatr Neurol. 2017;21: 232–41.
3. Quirouet A, Bhattacharyya PK, Dielubanza EJ, Gill BC, Jones SE, Goldman HB: Sacral neuromodulation device heating during lumbar and pelvic magnetic resonance imaging—a phantom study. Urology. 2017;107: 61.
4. De Wachter S, Knowels CH, Elterman DS, et al: New Technologies and Applications in Sacral Neuromodulation: An Update. Adv Ther 2020;37(2):637-643.
5. Kalin R, Stanton MS: Current clinical issues for MRI scanning of pacemaker and defibrillator patients. Pacing Clin Electrophysiol. 2005;28:326–8.
6. Muehling OM, Wakili R, Greif M, von Ziegler F, Morhard D, Brueckmann H, et al: Immediate and 12 months follow up of function and lead integrity after cranial MRI in 356 patients with conventional cardiac pacemakers. J Cardiovasc Magn Reson. 2014;16: 39.
7. Nazarian S, Hansford R, Rahsepar AA, Weltin V, McVeigh D, Gucuk Ipek E, et al: Safety of magnetic resonance imaging in patients with cardiac devices. N Engl J Med. 2018;377: 2555.
8. Chermansky CJ, Krlin RM, Holley TD, Woo HH, Winters JC: Magnetic resonance imaging following InterStim®: an institutional experience with imaging safety and patient satisfaction. Neurourol Urodyn. 2011; 30:1486–8.
9. Elkelini MS, Hassouna MM: Safety of MRI at 1.5Tesla in patients with implanted sacral nerve neurostimulator. Eur Urol. 2006; 50:311–6.
10. Alsyouf M, Keheila M, Marinone M, Blackburn A, Staack A: Magnetic resonance imaging of the ankle performed on an InterStim patient. Can J Urol. 2016; 23: 8168–70.