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ORIGINAL RESEARCH

Off-Label Magnetic Resonance Imaging (MRI) in Patients with Persistent Pain with Spinal Cord Stimulators: A Case Series

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Objective: Advances in spinal cord stimulator (SCS) technology and increasing prevalence of magnetic resonance imaging (MRI) diagnostic testing require empirical evidence describing the presence of MRI-related SCS adverse events related to off-label use of imaging. MRI safety recommendations vary based on the type of stimulator used with scant availability regarding adverse events associated with off-label MRI use. The aim of this case series is to describe the type and frequency of adverse events associated with off-label MRI use in patients with implanted SCSs.

Materials and Methods: Convenient samples of records of patients who had SCS and subsequently underwent MRI were included. Descriptive data including patient demographics, stimulator information, and frequency of adverse events were described.

Results: Sixty-nine individuals with implanted SCSs were included. The total number of scans was 78. Sixty-two percent of the sample was female. Over 92% of the MRI scans were considered off-label and the overall adverse event rate for off-label use was 9.72%. No serious adverse events were reported. Seven clinical adverse events were reported, all of which were related to the spinal cord stimulation and resolved.

Conclusion: This case series demonstrates that individuals implanted with SCSs experienced no serious adverse events associated with off-label MRI use. While these results represent a convenient sample, they provide important preliminary information about using MRI when medically necessary for patients with older spinal cord stimulator models. Specifically, these data demonstrate that the rate of observed adverse events related to MRI was low and suggest that the benefits of acquiring these images for pain management may outweigh the risks of not acquiring MRI for appropriate pain management.

Keywords: spinal cord stimulation, chronic pain, magnetic resonance imaging

Introduction

Spinal cord stimulators (SCS) are implantable devices used to manage intractable and persistent pain and involve low-voltage current intended to block nociceptive input.[1] Spinal cord stimulators have been shown to be safe and effective for persistent pain conditions, including spinal pain and complex regional pain syndrome.[2–6]

Safety concerns exist for patients with implanted SCSs and the use of magnetic resonance imaging (MRI) due to the magnetic field interfering with the device and its functionality. For example, one concern is that the magnetic field may alter the position of the device and/or accelerate the device into the bore of the magnet, causing severe damage to patient tissue. Also, the radiofrequency current may lead to heating of SCS, resulting in thermal and/or electrical burns to the patient and potential device malfunction. Another concern is that the presence of the device may affect the quality of the image(s) depending on the location of the image relative to the device. If the goal of the MRI is to evaluate areas in which to potentially intervene, image quality is of obvious importance.[7,8] Although individual studies have reported safety outcomes, no consensus guidelines exist on how to safely perform imaging of patients with various implanted SCS. Rather, manufacturers provide device-specific guidelines, but these guidelines vary on whether or not MRI is contraindicated, and which parts of the body are considered safe to image. For example, some devices have been

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developed to allow for full body scans while others allow only for head scans. In some devices, MRI may be an absolute contraindication and in others, safety has yet to be determined. De Andres et al[9] described the frequency and type of adverse events associated with a single manufacturer and reported that in 31 patients with SCSs who underwent MRI, seven reported events ranging from feeling stimulation during the MRI and increased thermal sensations at the lead sites. Others have reported on SCS-related adverse events but not necessarily related to MRI.[10]

On-label versus off-label MRI in patients with SCSs is a related concern and one that has not been widely explored. Patients post-laminectomy syndrome or with failed back surgery syndrome (FBSS) are the most common historical indication for SCS therapy and are among those that may require repeat imaging.[11,12] Prior to 2012, all spinal cord stimulation systems were not considered "on label" for MRI use. Spinal cord stimulator models, including Precision, Protégé, and Eon Mini systems, were excluded for MRI. In 2012, the Medtronic system gained MRI conditionality. As newer generation implantable pulse generators (IPGs) have gained MRI conditionality, some of these are specific only for head or extremities. Others require specifications inherent to the leads, such as normalized impedance values or placement within a particular anatomical region, T7-T12.

Given the limited information available regarding MRI conditionality in patients with SCS, the purpose of this case series is to describe the frequency and type of long-term adverse events associated with off-label MRI use in patients with SCSs.

Methods

This case series included a convenience sample of patient records from an outpatient interventional pain clinic. The records represent with a permanent SCS who subsequently underwent MRI. The frequency and type of long-term adverse events reported by patients were evaluated following MRI. This study involved a retrospective review of patient records and thus a waiver of informed consent was obtained and the study was approved by the Advarra Institutional Review Board; the data accessed complied with relevant data protection and privacy regulations. The primary outcomes of interest were the frequency and type of adverse events following MRI. Adverse events were coded as serious or clinical, SCS or MRI-related, and as mild, moderate, or severe. Demographic information, duration of clinical symptoms, manufacturer and model type of SCS, on- versus off- label MRI use, and adverse event frequency were described. All data were analyzed in Microsoft Excel.

Results

Sixty-nine patient records were included in this study and Table 1 includes demographic information about the sample. Of these 69 records, 7 included more than one MRI, thus the total scan count for this sample was 78. Forty-two (62%) were female and the average age of the sample was 60.5 years. The duration of pain symptoms ranged from 5 to 47 years, with an average of 12 years. The primary medical diagnoses included failed back surgery syndrome (FBSS), failed neck surgery syndrome (FNSS), and chronic regional pain syndrome. The primary rationale to opt for off-label MRI versus other imaging methods is that MRI in this sample was the best available option to visualize the spinal cord and nerves; MRI may show spinal abnormalities, injuries, and disease that may not be seen with other methods.

The duration from implant to MRI and duration from MRI to long-term follow-up are in Table 2. The time from permanent generator implant to MRI ranged from less than 1 month to 87 months (mean 19.4 months, standard deviation 17.7 months). The time from MRI to long-term follow-up ranged from 2 months to 17 months (mean 10.4 months, standard deviation 3.2 months). All patients underwent MRI in a 1.5 Tesla scanner (Siemens Medical Solutions USA, Inc, Malvern, PA).

The manufacturers and IPG models are listed in Table 3. Based on the IPG model, lead types, locations, and configurations, the overwhelming majority of patients in this sample (94.1%) underwent off-label MRI use. The frequency of adverse events for patients who underwent off-label MRI use was 10.9%. The most common reported as undesirable changes in stimulation (4/7), followed by persistent pain or numbness (2/7), and radicular chest wall or abdominal stimulation (1/7). All seven events were considered non-serious and all were resolved. For all adverse events, a representative from the company was called for troubleshooting and resolved with re-programming. If adequate stimulation could not be achieved, patients were sent for additional imaging to examine the leads and IPG under

Table 1 Demographic Information

Patient #	Age	Sex	Diagnosis	Pain Duration (Years)
1	54	F	Failed back surgery syndrome	11
2	62	M	Failed back surgery syndrome	5
3	62	F	Low Back pain; neck pain	19
4	49	F	Failed back surgery syndrome	20
5	66	M	Failed back surgery syndrome	10
6	53	M	Failed back surgery syndrome	8
7*	44	F	Failed back surgery syndrome; cervicalgia	20
7A*	45	F	Post laminectomy syndrome	20
7B*	46	F	Post laminectomy syndrome	21
7C*	47	F	Failed back surgery syndrome; cervicalgia	22
8	65	M	Post laminectomy syndrome	2
9*	59	M	Failed back surgery syndrome	10
9A*	60	M	Failed back surgery syndrome	11
10	50	F	Chronic regional pain syndrome, bilateral	13
11	50	F	Low Back pain	13
12	71	F	Lumbalgia	7
13	57	F	Failed back surgery syndrome	11
14	51	M	Failed back surgery syndrome	15
15	71	F	Low back pain	6
16	51	M	Failed back surgery syndrome	7
17	59	F	Multilevel disc disease	8
18	71	F	Low back pain	10
19	83	F	Multilevel disc disease	4
20	54	F	Low back pain	13
21	79	M	Low back pain	14
22	69	M	Failed back surgery syndrome	15
23	51	M	Chronic regional pain syndrome	5
24	42	F	Failed back surgery syndrome	4
25	53	F	Failed back surgery syndrome	36
26	77	F	Failed back surgery syndrome	19
27	44	M	Failed back surgery syndrome	11
28	68	F	Multilevel disc disease	12
29	63	M	Low back pain	5

(*Continued*)

Table 1 (Continued).

Patient #	Age	Sex	Diagnosis	Pain Duration (Years)
30	65	F	Failed back surgery syndrome	8
31	88	M	Degenerative disc disease	5
32	52	M	Failed back surgery syndrome	4.5
33	69	F	Multilevel disc disease	9
34	63	F	Failed back surgery syndrome	10
35	57	F	Failed back surgery syndrome	5
36	60	F	Failed back surgery syndrome	12
37*	80	M	Facet arthroplasty	13
37A*	80	M	Facet arthroplasty	13
38	66	F	Multilevel disc herniation	10
39	55	F	Lumbalgia	7
40*	79	F	Multilevel disc herniation	11
40A*	80	F	Multilevel disc herniation	12
41*	57	M	Failed back surgery syndrome	6
41A*	59	M	Failed back surgery syndrome	8
42*	38	M	Failed back surgery syndrome	18
42A*	40	M	Failed back surgery syndrome	20
43	47	F	Failed back surgery syndrome	9
44	61	F	Failed back surgery syndrome	28
45	77	F	Multilevel disc disease	13
46	75	F	Failed back surgery syndrome	8
47*	70	F	Multilevel disc herniation	12
47A*	70	H	Multilevel disc herniation	12
48	58	F	Failed back surgery syndrome	8.75
49	65	M	Failed back surgery syndrome	3
50	63	M	Failed back surgery syndrome	3.25
51	67	M	Failed back surgery syndrome; peripheral neuropathy	7
52	69	F	Failed back surgery syndrome	9
53	39	M	Failed back surgery syndrome	10
54	72	F	Failed back surgery syndrome	10
55	51	F	Failed back surgery syndrome	6
56	51	F	Failed back surgery syndrome	13
57	59	F	Failed back surgery syndrome	28

(*Continued*)

Table 1 (Continued).

Patient #	Age	Sex	Diagnosis	Pain Duration (Years)
58	68	F	Other intervertebral disc displacement, lumbar	47
59	66	F	Other intervertebral disc displacement, lumbar	12
60	56	M	Failed back surgery syndrome	20
61	53	M	Failed back surgery syndrome	14
62	49	F	Failed neck surgery syndrome	4.5
63	63	M	Failed neck surgery syndrome	17
64	48	F	Failed neck surgery syndrome	24
65	45	F	Failed back surgery syndrome, chronic regional pain syndrome	18
66	54	M	Failed back surgery syndrome	13
67	72	M	Failed back surgery syndrome	7
68	49	F	Failed neck surgery syndrome, failed back surgery syndrome	15
69	67	M	Radiculopathy	8

Note: *Indicates the same individual who underwent more than one MRI.

Table 2 MRI and Follow-Up Information

Patient #	Duration from IPG Implant to MRI (Months)	Duration from MRI to Follow-up (Months)	Clinical Event	Severity of Clinical Event	Related to SCS	Related to MRI?	Event Resolved?
1	9	13					
2	7	11					
3	4	11					
4	25	9	Radicular chest wall or abdominal stimulation	Mild	No	No	Yes
5	35	15					
6	4	8					
7*	12	11	Undesirable changes in stimulation	Mild	Yes	No	Yes
7A*	1	1					
7B*	11	13					
7C*	19	13					
8	19	13					
9*	25	14					
9A*	5	11					
10	4	11					
11	26	9	Undesirable changes in stimulation	Mild	Yes	No	Yes

(*Continued*)

Table 2 (Continued).

Patient #	Duration from IPG Implant to MRI (Months)	Duration from MRI to Follow-up (Months)	Clinical Event	Severity of Clinical Event	Related to SCS	Related to MRI?	Event Resolved?
12	22	12					
13	5	7					
14	87	11					
15	13	8					
16	39	4					
17	28	12					
18	4	13					
19	3	16					
20	3	13					
21	14	12					
22	49	14					
23	5	9					
24	5	11					
25	0	2					
26	26	13					
27	8	11					
28	3	11					
29	7	4					
30	1	11					
31	9	11					
32	1	10					
33	7	11	Persistent pain or numbness at the electrode or IPG site	Moderate	Yes	No	Yes
34	17	8					
35	9	10	Persistent pain or numbness at the electrode or IPG site	Moderate	Yes	No	Yes
36	12	11					
37*	37	12					
37A*	33	12					
38	5	11					
39	9	12					
40*	34	21					
40A*	55	6					
41*	28	8					

(*Continued*)

Table 2 (Continued).

Patient #	Duration from IPG Implant to MRI (Months)	Duration from MRI to Follow-up (Months)	Clinical Event	Severity of Clinical Event	Related to SCS	Related to MRI?	Event Resolved?
41A*	4	1					
42*	33	12					
42A*	60	5					
43	17	10					
44	30	13					
45	47	13					
46	10	11					
47*	2	6					
47A*	7	9					
48	12	17					
49	5	0					
50	20	10					
51	5	8	Undesirable changes in stimulation	Mild	Yes	No	Yes
52	46	9					
53	17	10					
54	34	11					
55	30	11					
56	30	12					
57	14	12					
58	34	7	Undesirable changes in stimulation	Mild	Yes	No	Yes
59	0	11					
60	27	12					
61	16	11					
62	4	12					
63	10	9					
64	3	13					
65	49	13					
66	69	11					
67	42	2					
68	33	15					
69	26	24					

Note: *Indicates the same individual who underwent more than one MRI.

Table 3 Spinal Cord Stimulator Information

Patient	IPG Manufacturer	Model	IPG Placement	Lead 1 Type	Lead 1 Location	Lead 2 Type	Lead 1 Location	Lead 1 Configuration	Lead 2 Configuration	MRI Location	Off Label Use?	*Clinical Event?*
1	Boston Scientific	Precision	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar+ Cervical	Yes	
2	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	Yes	
3	St. Jude Medical	Protégé	Upper buttock	Percutaneous	C2-C3	Percutaneous	C2-C3	1x8	1x8	Lumbar+ Cervical	Yes	
4	Boston Scientific	Precision	Upper buttock	Percutaneous	L2-L3	Percutaneous	L2-L3	1x8	1x8	Lumbar+ Cervical	Yes	***Yes***
5	Boston Scientific	Precision	Upper buttock	Percutaneous	T7-T8	Percutaneous	T7-T8	1x8	1x8	Lumbar	Yes	
6	St. Jude Medical	Eon Mini	Upper buttock	Percutaneous	T12-L1	Percutaneous	T12-L1	1x8	1x8	Lumbar	Yes	
7*	St. Jude Medical	Protégé	Upper buttock	Percutaneous	C2-C3	Perc paddle	T7-T8	1x8	1x8	Lumbar+ Cervical	Yes	***Yes***
7A*	St. Jude Medical	Protégé	Flank	Percutaneous	C2-C3	Percutaneous	T7-T8	1x8	1x8	Lumbar	Yes	
7B*	St. Jude Medical	Protégé	Flank	Percutaneous	C2-C3	Percutaneous	T7-T8	1x8	1x8	Cervical	Yes	
7C*	St. Jude Medical	Protégé	Upper buttock	Percutaneous	C2-C3	Perc paddle	T7-T8	1x8	1x8	Lumbar+ cervical	Yes	
8	Boston Scientific	Precision	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	
9*	St. Jude Medical	Eon Mini	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar+ Cervical	Yes	
9A*	St. Jude Medical	Proclaim	Flank	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	
10	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T12-L1	Percutaneous	T12-L1	1x8	1x8	Lumbar	Yes	
11	St. Jude Medical	Eon Mini	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	***Yes***
12	Boston Scientific	Precision	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar+ Cervical	Yes	

13	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T9	Perc paddle	T7-T9	1x8	1x8	Lumbar+ Cervical	Yes	
14	Boston Scientific	Precision	Upper buttock	Percutaneous	T9-T10	Percutaneous	T9-T10	1x8	1x8	Lumbar	Yes	
15	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T9	Perc paddle	T7-T9	1x8	1x8	Lumbar+ Cervical	Yes	
16	Boston Scientific	Precision	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar+ Thoracic	Yes	
17	Boston Scientific	Precision	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	
18	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T12-L1	Perc paddle	T12-L1	1x8	1x8	Lumbar	Yes	
19	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T8/T9	Perc paddle	T9/T10	1x8	1x8	Lumbar	Yes	
20	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar+ Cervical	Yes	
21	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T12-L1	Perc paddle	T12-L1	1x8	1x8	Lumbar	Yes	
22	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	
23	St. Jude Medical	Eon Mini	Upper buttock	Percutaneous	C1-C3	Percutaneous	C1-C3	1x8	1x8	Cervical	Yes	
24	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T9	Perc paddle	T7-T9	1x8	1x8	Lumbar	Yes	
25	St. Jude Medical	Eon Mini	Upper buttock	Percutaneous	T8-T10	Percutaneous	T8-T10	1x8	1x8	Lumbar	Yes	
26	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	Yes	
27	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	

(*Continued*)

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Table 3 (Continued).

Patient	IPG Manufacturer	Model	IPG Placement	Lead 1 Type	Lead 1 Location	Lead 2 Type	Lead 1 Location	Lead 1 Configuration	Lead 2 Configuration	MRI Location	Off Label Use?	*Clinical Event?*
28	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T8	Perc paddle	T7-T8	1x8	1x8	Lumbar	Yes	
29	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T8-T9	Perc paddle	T8-T9	1x8	1x8	Lumbar	Yes	
30	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T8	Perc paddle	T7-T8	1x8	1x8	Lumbar	Yes	
31	Boston Scientific	Precision	Upper buttock	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	Yes	
32	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T7-T9	Perc paddle	T7-T9			Lumbar	Yes	
33	Boston Scientific	Precision	Upper buttock	Percutaneous	T7-T8	Percutaneous	T7-T8	1x8	1x8	Lumbar	Yes	***Yes***
34	St. Jude Medical	Eon Mini	Upper buttock	Percutaneous	T9-T10	Perc paddle	T9-T10	1x8	1x8	Lumbar	Yes	
35	St. Jude Medical	Protégé MRI	Upper buttock	Percutaneous	T7-T8	Percutaneous	T7-T8	1x8	1x8	Lumbar	Yes	***Yes***
36	St. Jude Medical	Proclaim 7	Right flank	Percutaneous	T7-T9	Perc paddle	T7-T9	1x8	1x8	Lumbar	Yes	
37*	St. Jude Medical	Protégé MRI	Right flank	Percutaneous	T7-T8	Perc paddle	T7-T8	1x8	1x8	Cervical	Yes	
37A*	St. Jude Medical	Protégé MRI	Right flank	Percutaneous	T7-T8	Perc paddle	T7-T8	1x8	1x8	Cervical	Yes	
38	St. Jude Medical	Protégé	Lower flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	Yes	
39	St. Jude Medical	Protégé MRI	Right flank	Percutaneous	T7-T9	Perc paddle	T7-T9	1x8	1x8	Lumbar	Yes	
40*	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	Yes	
40A*	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar+ cervical	Yes	
41*	St. Jude Medical	Proclaim 5	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	No	

41A*	St. Jude Medical	Proclaim 5	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar+ thoracic	No	
42*	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	Yes	
42A*	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T7-T10	Percutaneous	T7-T10	1x8	1x8	Lumbar+ thoracic	Yes	
43	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T8-T9	Perc paddle	T7-T8	1x8	1x8	Lumbar	Yes	
44	St. Jude Medical	Protégé IPG	Right flank	Perc paddle	T7-T9			1x8	1x8	Lumbar	Yes	
45	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar	Yes	
46	Boston Scientific	Precision	Right flank	Laminectomy	T8-T9	Laminectomy	T8-T9	1x8	1x8	Lumbar	Yes	
47*	St. Jude Medical	Proclaim 7	Right flank	Percutaneous	T7-T8	Percutaneous	T7-T8	1x8	1x8	Cervical	No	
47A*	St. Jude Medical	Proclaim 8	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Lumbar+ thoracic	No	
48	St. Jude Medical	Protégé MRI	Right flank	Percutaneous	T7-T8	Perc paddle	T7-T8	1x8	1x8	Lumbar	Yes	
49	St. Jude Medical	Proclaim 7	Right flank	Percutaneous	C7-T1	Percutaneous	C7-T1	1x8	1x8	Lumbar	Yes	
50	St. Jude Medical	Proclaim 7	Right flank	Percutaneous	T7-T9	Percutaneous	T7-T9	1x8	1x8	Right shoulder	No	
51	St. Jude Medical	Proclaim 7	Right flank	Percutaneous	T12-L1	Percutaneous	T12-L1	1x8	1x8	Lumbar	Yes	***Yes***
52	St. Jude Medical	Protégé IPG	Right flank	Percutaneous	T7-T8	Perc paddle	T7-T8	1x8	1x8	Cervical	Yes	
53	St. Jude Medical	Proclaim	Right flank	Percutaneous	T7-T9	Perc paddle	T7-T9	1x8	1x8	Lumbar	Yes	
54	St Jude Medical	Eon Mini	Right flank	Percutaneous	T7-T8	Perc paddle	T7-T8	1x8	1x8	Lumbar	Yes	
55	St. Jude Medical	Protégé IPG	Right flank	Percutaneous	T8-T9	Perc paddle	T8-T9	1X8	1X8	Lumbar	Yes	
56	Boston Scientific	Precision	Right flank	Percutaneous	T8-T10	Percutaneous	T8-T10	1x8	1x8	Lumbar	Yes	

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Table 3 (Continued).

Patient	IPG Manufacturer	Model	IPG Placement	Lead 1 Type	Lead 1 Location	Lead 2 Type	Lead 1 Location	Lead 1 Configuration	Lead 2 Configuration	MRI Location	Off Label Use?	*Clinical Event?*
57	St. Jude Medical	Protégé IPG	Right flank	Percutaneous	T7-T9	Perc paddle	T7-T9	1x8	1x8	Lumbar	Yes	
58	St. Jude Medical	Protégé IPG	Right flank	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	***Yes***
59	St. Jude Medical	Prodigy	Right flank	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar, Thoracic, Cervical	No	
60	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T12-L1	Percutaneous	T12-L1	1x8	1x8	Lumbar	Yes	
61	St. Jude Medical	Protégé IPG	Right flank	Percutaneous	T6-T7	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	
62	St. Jude Medical	Protégé	Right flank	Percutaneous	C2-C3	Percutaneous	C2-C3	1x8	1x8	Right hip+ Lumbar	Yes	
63	St. Jude Medical	Proclaim 7	Right flank	Percutaneous	C2-C3	Percutaneous	C2-C3	1x8	1x8	Right knee	Yes	
64	St. Jude Medical	Proclaim	Right flank	Percutaneous	C2-C3	Percutaneous	C2-C3	1x8	1x8	Lumbar	Yes	
65	St. Jude Medical	Eon Mini	Right flank	Percutaneous	T12-L1	Percutaneous	T12-L1	1x8	1x8	Lumbar	Yes	
66	Boston Scientific	Precision	Upper buttock	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	
67	St. Jude Medical	Protégé	Upper buttock	Percutaneous	T8-T10	Percutaneous	T8-T10	1x8	1x8	Lumbar	Yes	
68	Boston Scientific	Precision	Upper buttock	Percutaneous	L2-L3	Percutaneous	L2-L3	1x8	1x8	Cervical	Yes	
69	St. Jude Medical	Eon mini	Right flank	Percutaneous	T8-T9	Percutaneous	T8-T9	1x8	1x8	Lumbar	Yes	

Note: *Indicates the same individual who underwent more than one MRI.

fluoroscopy. After testing the functionality of equipment, devices were re-programmed until optimal results were achieved.

Discussion

This case series indicates that off-label MRI use did not result in long-term serious adverse events. While these represent pilot data, this work is notable and relevant to clinical management of chronic pain for several reasons. These data add to existing work in this area regarding MRI safety in patients with SCS and have potentially important implications for both diagnostic radiology and interventional pain medicine. A recent case report from Dr Andres et al[7] reported on the within-session adverse events associated with full-body MRI immediately following SCS implant. The patient in that case reported no serious or clinical events during the MRI. Second, the current case series expands on previous publications by examining off-label imaging and the frequency of long-term serious and clinical adverse events associated with this imaging. Previous recommendations for MRI in patients with SCS suggested that physicians should carefully select patients for MRI based on their potential to experience adverse events, including movement of the device, risk of thermal injury or burning, and alteration of the neurostimulation program.[13] A small percentage of individuals from the current study experienced mild to moderate clinical events; however, all of the clinical events were related to the device rather than the MRI and the frequency rate of adverse events was similar to published trials of SCS long-term safety.[14]

Given the low rate of adverse events when MRI was used in an off-label manner, these results suggest that the benefits of obtaining MRI for the purposes of identifying structure(s) that may be contributing to a patient's pain may outweigh the risks of not obtaining imaging in patients who have older SCS units. Future work may expand on the current study by exploring differences in adverse events in patients with on-label versus off-label MRI use. Although the vast majority of patients in the current study underwent off-label MRI, it is unclear if the frequency of adverse events may be different compared to individuals undergoing on-label MRI. These data would provide further information to aid clinical decision-making for diagnostic imaging in patients with persistent pain. Last, and as others have recommended,[15,16] consensus guidelines for the use of MRI for patients with SCS should be developed and evaluated beyond individual manufacturer's recommendations to provide in-depth information related to the safety parameters and utility of MRI in patients with chronic pain conditions.

Limitations

The current study included a convenience sample of patient records. Records were not included if follow-up data was not available (eg, the patient did not return to the clinic) or if demographic or other clinical information was not available in the patient record. The clinic from which these data were collected did not systematically assess (ie, at a specific time frame or manner) the presence of adverse events; thus, it is possible that the frequency of adverse events could be higher or lower based on the systematic evaluation of adverse events. Last, our follow-up time was relatively short at an average of 10.4 months. While we expect that adverse events associated with MRI would occur in the short-term (ie during the scan or shortly thereafter), it is possible that the MRI was associated with longer term effects that our follow-up period did not adequately capture.

Disclosure

The author reports no conflicts of interest in this work.

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