The Rate of Magnetic Resonance Imaging in Patients with Deep Brain Stimulation

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Key Words

Deep brain stimulation · Dystonia · Essential tremor ·
Magnetic resonance imaging · Neuromodulation ·
Parkinson's disease

Abstract

Background: For Parkinson's disease (PD), essential tremor (ET), and dystonia patients with deep brain stimulation (DBS) implants, magnetic resonance imaging (MRI) requires additional safety considerations due to potentially hazardous interactions. **Objective:** A propensity-matched cohort of DBS-implanted patients was analyzed to determine the likelihood of needing MRI. **Methods:** Patients with new DBS full-system implants (n = 576) were identified in the Truven Health MarketScan[®] Commercial Claims and Medicare Supplemental Databases (2009–2012). Patients diagnosed with PD, ET, or dystonia and no DBS implant were identified (DBS-indicated patients: n = 11,216). The DBS-indicated patients were continuously enrolled for 4 years and matched for age, gender, and propensity score based on comorbid conditions to DBS-implanted patients (n = 4,878 and 543, respectively). A Kaplan-Meier survival curve of time to first MRI was extrapolated to 10 years. **Results:** An estimated 56–57% of DBS-indicated patients need an MRI within 5 years and 66–75%

within 10 years after implantation. While 92% of DBS-implanted patients' MRI after implantation was of the head, for DBS-indicated patients, 62% of MRIs were of the body, potentially unrelated to the primary diagnosis. **Conclusions:** This analysis highlights the projected utilization of MRI in the DBS population for head and full-body images.

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Published by S. Karger AG, Basel

Introduction

Magnetic resonance imaging (MRI) is a valuable and often most appropriate imaging modality for numerous conditions based on professional society and consensus guidelines, including the American College of Radiology (ACR) guidelines [1]. In Europe, various medical societies [2–4] provide guidelines describing the performance of MRI in patients with implants or for MRI-indicated conditions. Additionally, the EC Referral Guidelines Workshop has published an article describing a need for imaging guidelines to be developed for all EU member states [5].

Neuroimaging studies are conducted to evaluate the structure and function of the brain in patients with neurodegenerative diseases, including Parkinson's disease

Table 1. Ratings for use of MRI for several movement disorders [7]

Clinical condition	Radiologic procedure	Rating
Parkinsonian syndrome (atypical clinical features; not responsive to levodopa)	MRI head without contrast	8
	CT head without contrast	5
PD	MRI head with and without contrast	7
	CT head with and without contrast	5
Probable Alzheimer's disease	MRI head without contrast	8
	CT head without contrast	6
Suspected vascular dementia	MRI head with and without contrast	8
	CT head with and without contrast	5
Rating scale: 1–3 = usually not appropriate; 4–6 = may be appropriate; 7–9 = usually appropriate.		

(PD), essential tremor (ET), and dystonia. Functional neuroimaging with MRI holds potential for better understanding of neurodegenerative disorders. Modalities like diffusion tensor imaging and functional MRI are becoming increasingly available, but, in the case of functional MRI, are not considered routine clinical practice at this time [6]. Nevertheless, the ACR Appropriateness Criteria for Movement Disorders rate MRI as usually appropriate for movement disorders, including PD, Parkinsonian syndrome, as well as Alzheimer's disease and dementia (table 1) [7]. In the example of Alzheimer's disease, MRI of the head without contrast is rated an 8, with no comparable option as the next highest rated image modality which may be appropriate is CT (rated a 5).

Deep brain stimulation (DBS) is used to treat symptoms associated with PD, ET, and dystonia [8–17]. PD, ET, and dystonia patients with DBS implants may not be eligible for full-body MRI due to the potential hazardous interactions. Between 2009 and 2012, some DBS therapy systems carried MRI conditional labeling for brain imaging when used with a transmit-receive head coil. However, implantation of these systems was contraindicated for patients exposed to MRI using a full-body transmit radiofrequency coil, a receive-only head coil, or a head transmit coil that extends over the chest area.

To provide an accurate estimate of the projected utilization of MRI in the DBS-implanted population, insurance claims databases were used to perform analysis of a propensity-matched population cohort to the DBS-implanted patients. Using 4 years of paid and adjudicated claims, exponential projection estimates were used to approximate the number of DBS patients who may receive at least 1 MRI within 5 and 10 years of DBS implantation.

Patients and Methods

Data Source

Data from the Truven Health MarketScan® Research Databases, which contain individual-level, de-identified, health care claims information from employers, health plans, hospitals, Medicare, and Supplemental and Medicaid programs, were used [18]. Often used for research, these databases are Health Insurance Portability and Accountability Act compliant. A protocol describing the study objectives, criteria for patient selection, data elements of interest, and statistical methods was submitted to the New England Institutional Review Board and deemed exempt from review (exemption No. 14-285).

Patient Selection and Identification

Using patient level data from the MarketScan Databases during 2009–2012, a cohort of patients with a new DBS full-system implant (DBS-implanted patients: $n = 576$) was identified. Continuous enrollment was required for 12 months before the date of the DBS implant. A second cohort required 4 years of continuous health plan coverage from 2009 to 2012. The second cohort excluded any DBS or MRI contraindication, and required a diagnosis of PD, ET, or dystonia based on International Classification of Diseases (ICD-9) diagnosis codes and no DBS implant (DBS-indicated patients: $n = 11,216$). The codes for these inclusion and exclusion criteria are listed in a supplementary table (for all online suppl. material, see www.karger.com/doi/10.1159/000444760). Patients with a diagnosis code for acute stroke or transient ischemic attack (TIA) in the year 2012 were identified in the DBS-indicated group. MRI utilization was summarized within ± 3 days of stroke or TIA.

Statistical Analysis

All data were imported and maintained in SAS® data files. Tabulation of summary statistics, graphical presentations, and data analyses were performed using SAS® Software (version 9.2; SAS Institute, Cary, N.C., USA).

Fig. 1. Flowchart of patient inclusion/exclusion.

Propensity Matching

Because the DBS-implanted cohort and the DBS-indicated cohort are not assigned randomly, cohorts may consist of patients that are systematically different from each other with respect to their demographics and comorbidity profiles. Direct and propensity score matching were used to reduce the risk of selection bias. An SAS macro from the Mayo Clinic (gmatch) was used to generate the match [19]. gmatch employs a greedy algorithm to choose a fixed number of controls for each patient in a treatment cohort (e.g. 1:1 or 2:1), whereby each patient is matched to their nearest neighbor with respect to all factors simultaneously, using various distance measures and calipers.

DBS-implanted patients were matched (1:10) to DBS-indicated patients using a combination of direct (age $\pm$ 3 years and gender) and propensity score matching (comorbid conditions). However, 10 matches were not always found for each DBS patient. Propensity scores were calculated from a logistic regression model as the probability that a patient had a DBS implant given the patient's comorbidity profile. Assessment of bias reduction was conducted by evaluating the differences in the distributions of patient characteristics between the cohorts before versus after matching.

Predicting MRI Utilization

After matching, the survival probability to the first MRI was estimated in the DBS-indicated cohort over a 4-year period (2009–2012). Using the survival estimates at each point in time from our

Table 2. Patient demographics

Category	Total		DBS implanted		DBS indicated	
	n	%	n	%	n	%
Total patients	5,421	100	543	100	4,878	100
Age group						
<18 years	83	2	12	2	71	1
18–29 years	82	2	7	1	75	2
30–39 years	67	1	7	1	60	1
40–49 years	324	6	36	7	288	6
50–59 years	1,317	24	136	25	1,181	24
60–69 years	2,112	39	202	37	1,910	39
70–79 years	1,224	23	119	22	1,105	23
$\geq$ 80 years	212	4	24	4	188	4
Gender						
Male	3,658	67	368	68	3,290	67
Female	1,763	33	175	32	1,588	33
Insurance coverage						
Commercial	2,990	55	305	56	2,685	55
Medicare	2,431	45	238	44	2,193	45
Insurance product type						
Missing	143	3	34	6	109	2
Comprehensive	1,384	26	98	18	1,286	26
EPO	55	1	5	1	50	1
HMO	789	15	59	11	730	15
POS	371	7	28	5	343	7
PPO	2,522	47	299	55	2,223	46
POS with capitation	15	0	2	0	13	0
CDHP	114	2	11	2	103	2
HDHP	28	1	7	1	21	0
Region						
South	1,961	36	192	35	1,769	36
West	1,349	25	134	25	1,215	25
North central	1,284	24	131	24	1,153	24
Northeast	802	15	79	15	723	15
Unknown	25	0	7	1	18	0

EPO = Exclusive provider organization; HMO = health maintenance organization; POS = point of service; PPO = preferred provider organization; CDHP = consumer-driven health plan; HDHP = high deductible health plan.

sample, the data were fitted with multiple exponential functions to project a range of best-fit scenarios, as measured by the coefficient of determination, out to 10 years.

Results

There were 97,479,482 patients in MarketScan during 2009–2012. There were 1,102 patients that had an initial (leads and generator, not replacement) DBS implant, 576

of whom had at least 12 months of continuous enrollment prior to implantation and were verified to have received a DBS through code review. Of the remaining patients in MarketScan, 11,287,751 patients had enrollment for the entire 4-year period. Of those, 11,216 had a diagnosis of PD, ET, or dystonia, did not have a DBS implant, other MRI contraindication, or a condition that made them ineligible for DBS implantation (fig. 1; suppl. material).

After matching, there were a total of 4,878 DBS-indicated patients tracked over 4 years: 67% of patients were male, the majority of which were 50–79 years of age, and 55% had commercial insurance (table 2). Overall, 56% of patients had no comorbidities, and 26% had only one comorbidity (table 3). The most common comorbid conditions included diabetes without chronic complications (16%), cerebrovascular diseases (13%), chronic pulmonary disease (12%), and cancer (8%) (table 4). For the

DBS-indicated cohort, the rate of patients receiving MRI was identified after 1 year (19%), 2 years (32%), 3 years (42%), and 4 years (50%) (fig. 2). Using an exponential projection, the projected utilization of MRI within 5 years is 56–57% (fig. 2). Approximately 66–75% of DBS-implanted patients are expected to need at least one MRI within 10 years of the implant (fig. 2).

For DBS-implanted patients, a total of 501 (92%) patients received MRI within 12 months prior to implantation (table 5). Of DBS-implanted patients, 41% received only one MRI and 51% received more than one. After implantation, 5% of DBS-implanted patients had MRI within 30 days, and 5% from 31 days after implantation to the end of the enrollment period (table 6). In these patients, the majority of MRI were of the head/brain (93% <31 days, 91% ≥31 days). Of the DBS-indicated patients, 42% had MRI. Of the MRI performed in these patients,

Table 3. Number of comorbid conditions

Comorbid conditions	Total		DBS implanted		DBS indicated	
	n	%	n	%	n	%
0	3,062	56	251	46	2,811	58
1	1,408	26	173	32	1,235	25
2	578	11	68	13	510	10
≥3	373	7	51	9	322	7

Table 4. Types of comorbid conditions in the patients

Category	Total		DBS implanted		DBS indicated	
	n	%	n	%	n	%
All patients	5,421	100	543	100	4,878	100
Diabetes without chronic complications	855	16	84	15	771	16
Cerebrovascular disease	679	13	95	17	584	12
Chronic pulmonary disease	644	12	83	15	561	12
Cancer	435	8	49	9	386	8
Peripheral vascular disease	219	4	26	5	193	4
Diabetes with chronic complications	211	4	26	5	185	4
Renal disease	190	4	17	3	173	4
Congestive heart failure	170	3	29	5	141	3
Rheumatic disease	129	2	20	4	109	2
Mild liver disease	124	2	15	3	109	2
Myocardial infarction	100	2	16	3	84	2
Paraplegia/hemiplegia	50	1	19	3	31	1
Peptic ulcer	41	1	7	1	34	1
Metastatic carcinoma	18	0	2	0	16	0
Moderate/severe liver disease	13	0	1	0	12	0
Senility	8	0	4	1	4	0
AIDS/HIV	6	0	1	0	5	0

62% were of the body, 35% of the head/brain, and 3% of the jaw/neck (table 6). The rate of patients having MRI in the 2012 Truven Health MarketScan® Research Databases is 6% (9,299,077/167,568,797 in a population weighted to estimate a national rate of MRI).

Among the DBS-indicated patients, 1.9% (93/4,878) of patients had a diagnosis code for an acute stroke or TIA in 2012. Within ± 3 days of the diagnosis code for acute stroke or TIA, 37% (34/93) with an acute stroke or TIA had a claim for MRI.

Discussion

The use of diagnostic imaging has substantially increased over the past few decades, with the largest growth in emerging markets [20, 21]. It is important that patients receive the most appropriate imaging test for their condition. The decision on when MRI is most appropriate can be best understood when considering the following situations: (1) MRI has no equivalent or the alternative would negatively impact patient care and/or outcomes with lower yield, sensitivity, or specificity; (2) there is an alternative to MRI, but involves a procedure or operation and great costs and/or risks, or (3) computed tomography (CT) is an alternative but has a higher radiation dose and may involve less safe contrast injection compared to MRI, as the rate of reactions to CT contrast medium is much higher than to MRI [22, 23]. That being said, there are situations where CT, ultrasound, or nuclear medicine is better than MRI. Additionally, when patients cannot undergo MRI, alternative modalities are employed, such as when they are allergic to intravenous contrast medium. Recently, some devices have received FDA approval for

Fig. 2. MRI use in DBS-indicated patients to 4 years and projected utilization to 10 years.

Table 5. Frequency of MRI ≤ 12 months before DBS implantation

Category	n	%
Total patients	543	100
Total patients with MRI	501	92
Patients with only 1 MRI scan	224	41
Patients with ≥ 1 MRI scan	277	51
Patients with no MRI	42	8
Total MRI	904	
MRI scans performed/patient (average)	1.66	

Table 6. Frequency of MRI after DBS implantation or any time

	DBS implanted				DBS indicated	
	≤ 30 days after implantation		≥ 31 days after implantation		any time after 1/1/2009	
	n	%	n	%	n	%
All patients	543		543		4,878	
Total patients with MRI	26	5	26	5	2,069	42
Total MRI	29		35		3,670	
Head/brain	27	93	32	91	1,284	35
Body	1	3	3	9	2,293	62
Jaw/neck	1	3	0	3	93	3

full-body MRI under specific conditions of use. Practitioners should work with manufacturers to understand available options.

The rate of MRI in the 2012 Truven Health MarketScan[®] Research Databases weighted to provide a national estimate is 6%. Among DBS-indicated patients, the rate of MRI is 42%, the majority of which (62%) were performed on the body. In the DBS-implanted population, however, only 5% of patients received an MRI after implantation, and the majority of these MRI scans (91%) were performed of the head, where other imaging modalities may not have been appropriate. This would be expected given the restrictions for head MRI with a DBS and the desire for postoperative evaluation of the DBS lead. Projected MRI in the DBS-indicated and -implanted populations are high (42 and 5%, respectively). These results substantiate that patients who receive a DBS implant may not have historically received the preferred MRI method.

These results are similar to findings for patients with cardiac implants, where, until recently, MRI was contraindicated for patients with implanted pacemakers. For cardiology patients, there are a growing number of indications for MRI [24], but due to the previous lack of MRI-compatible pacemakers and cardioverter defibrillators, and despite a few isolated centers performing off-label scans, patients implanted with these devices who might benefit from an MRI generally did not receive one [25]. That situation changed after the approval of MRI-conditional pacemakers when implanted patients had very similar annual MRI rates to matched controls in follow-up studies of implanted patients (13 and 15%, respectively) [25, 26]. Furthermore, of those receiving a scan after implantation, 47% did not receive a previous MRI scan [26]. This demonstrates the rate and preference of obtaining MRI when unrestricted and demonstrates physician preference when given the ability to choose.

The number of breast MRI is on the rise [27], especially for high-risk women [28]. The 2014 Appropriateness Criteria from the ACR discuss breast imaging for diagnostic purposes, including breast cancer screening, and for radiation oncology [29]. Patients with breast implants are able to receive MRI to determine implant integrity and breast cancer detection. Sardanelli et al. [4] report on the evidence that MRI will detect implant rupture approximately 78–89% of the time as compared to X-ray mammography, which is expected to detect 25–30% of ruptures. In 2011, the FDA updated its MRI guidelines for patients with silicone gel breast implants, recommending women get their first breast MRI 3 years after receiving the implants and every 2 years thereafter to de-

tect silent ruptures [30]. Given this information, it is the individual clinicians' choice to determine whether their patients may require MRI in the future, particularly as their patient's clinical course continues to evolve both in the movement disorder realm, but also in the scope of their path through the larger medical ecosystem.

This analysis has several strengths, including the use of data that are both recent and based on a large group of patients from all regions of the US. The use of propensity-matched cohorts reduces the risk of bias while establishing groups based on actual patient populations with real-world data. This analysis is based on actual patient populations demonstrating the use of MRI. This analysis did not match the cohorts on disease progression in order to evaluate MRI-projected utilization not necessarily related to the primary disease. Additionally, the analysis uses 4 years of paid and adjudicated claims data to determine actual MRI completion, and have therefore met payer medical necessity criteria. MRI utilization within ± 3 days of stroke or TIA is assumed to be associated with stroke or TIA diagnosis. The rate of patients with stroke or TIA and with MRI in the year of 2012 is reported. Claims data have an inherent limitation in that they were designed for billing purposes and not research, thus clinical data are not available for analysis. Additionally, claims are only reflective of what was coded with the assumption the coding is accurate and complete. Finally, these findings are only generalizable to other United States commercially insured and Medicare populations.

Conclusion

This analysis highlights the significant projected utilization of MRI in movement disorder patients with a projected 10-year rate of 66–75%. This demonstrates the inherent need for MRI in this patient population.

Acknowledgment

All funding was provided by Medtronic, Inc.

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