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MAJOR PAPER

A National Survey on Safety Management at MR Imaging Facilities in Japan

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Purpose: To investigate safety management at Japanese facilities performing human MRI studies.

Methods: All Japanese facilities performing human MRI studies were invited to participate in a comprehensive survey that evaluated their MRI safety management. The survey used a questionnaire prepared with the cooperation of the Safety Committee of the Japanese Society for Magnetic Resonance in Medicine. The survey addressed items pertaining to the overall MRI safety management, questions on the occurrence of incidents, and questions specific to facility and MRI scanner or examination. The survey covered the period from October 2017 to September 2018. Automated machine learning was used to identify factors associated with major incidents.

Results: Of 5914 facilities, 2015 (34%) responded to the questionnaire. There was a wide variation in the rate of compliance with MRI safety management items among the participating facilities. Among the facilities responding to this questionnaire, 5% reported major incidents and 27% reported minor incidents related to MRI studies. Most major incidents involved the administration of contrast agents. The most influential factor in major incidents was the total number of MRI studies performed at the facility; this number was significantly correlated with the risk of major incidents ($P < 0.0001$).

Conclusion: There were large variations in the safety standards applied at Japanese facilities performing clinical MRI studies. The total number of MRI studies performed at a facility affected the number of major incidents.

Keywords: *accident, examination, magnetic resonance imaging, safety*

Introduction

Diagnostic MRI is used worldwide. The number of MRI units in Japan is about 7 times the global average, and the ratio of MRI scanners to the population is the highest in the world.[1] MRI presents safety risks associated with large static and changing magnetic fields, high-powered RF coil systems, and exogenous contrast agents.[2–7] Diagnosticians must be alert to these risks and their mitigations in order to protect their patients, themselves, and their colleagues from the avoidable harm. Consequently, strict compliance with safety regulations is required.[2–7]

In 2014, the Safety Committee of the Japanese Society for Magnetic Resonance in Medicine (JSMRM) issued the second edition of "MRI Safety Principles, Standards and Clinical Concerns".[8] However, it remained unknown how well the promulgated safety management standards were applied at Japanese MRI facilities. Therefore, we aimed to investigate safety management at facilities performing human MRI studies in Japan.

Materials and Methods

Facilities surveyed

All medical facilities in Japan with MRI equipment were invited to participate in a survey that evaluated their compliance with MRI safety standards. A list of these facilities was obtained

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from the website of the Ministry of Health, Labour and Welfare (https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/teikyouseido/index.html). A Japanese medical journal[9] was referred to identify the MRI scanners. Facilities whose addresses were unknown and facilities that had sold their MRI equipment were excluded. The total number of facilities invited to participate in the survey was 5914.

Questionnaire

Our survey questionnaire was prepared with the cooperation of the JSMRM. It included items specific to MRI safety management (Tables 1–5) and questions pertaining to the occurrence of major and minor incidents (Table 6). The questionnaire also contained information regarding the type of facility that hosted MRI equipment, MRI scanners, average time for 1 MRI examination, number of MRI studies, and personnel (Figs. 1–7).

Survey period and method

The survey covered the period from October 2017 to September 2018. On November 5, 2018, the survey questionnaires were sent by regular mail or by e-mail to 5914 facilities. Each survey packet sent by regular mail included a prepaid return envelope. Questionnaires sent by e-mail included commercially available Google forms (docs.google.com/forms); responses were collected electronically. The deadline for submitting the responses was November 30, 2018. Survey reminders were sent a few days before the deadline.

Statistical analysis

It was difficult to adopt conventional multivariate statistical methods because this study handled many types of questions including multiple-choice questions. Therefore, before conducting the survey, these survey questionnaires were designed to apply a machine learning analysis model. To adequately perform accurate statistical analysis for items with many variables, the variables in 7 questions were consolidated. To identify the factors associated with MRI-related major incidents that had affected the patient's health, the DataRobot enterprise artificial intelligence (AI) platform (DataRobot Automated Machine Learning version 6.0; DataRobot, Tokyo, Japan) was used to create machine learning models. The AI platform provides a method to create a more robust and accurate ensemble model by combining independent models created from multiple independent algorithms. The relative importance of a variable to the ensemble model was assessed using permutation importance as described by Breiman.[10] On the DataRobot platform, the following 5 steps were performed automatically:

1. The random seed controlling the random sampling condition in cross-validation (CV) partitioning was changed 10 times to run the "autopilot" 10 times.
2. Each time on autopilot, 7-fold CV was conducted with a 0% holdout. (Partitioning employs stratified extraction so that the ratio of true/false is the same for all folds.)
3. For model creation, hyperparameters were optimized; preprocessing and algorithm application were performed automatically.
4. With each autopilot run (n = 10), multiple ensemble models were generated; single machine learning models with different algorithmic predispositions (e.g., eXtreme gradient-boosted trees, random forest, and regularized regression such as Elastic Net and Neural Networks) were combined. The ensembles also applied various methods such as Average and Generalized Linear Model (GLM).
5. Permutation importance was calculated for the most accurate ensemble models created in step 4. Since going through these steps finally yielded 10 permutation importance values for each explanatory variable, its median value was calculated.

We then performed variable selection to ensure that no explanatory variables with relatively small median values were included in the model and again performed autopilot runs with different random seeds. We repeated the above steps to narrow down the results to only the important variables.

To understand the independent impact of individual variables on major incidents, we constructed a partial dependence plot as described by Friedman.[11] We used Light Gradient Boosted Machine Classifier, a machine learning model based on gradient boosting, to calculate the plotted values. The partial dependence plot can be interpreted as showing the effect of changing a variable in isolation; it demonstrates the relationship between the value of that variable and the probability value of the major incident. For each of the selected items, the risk ratio for major incidents was calculated; to obtain the correlation between two variables, the Pearson correlation coefficient (r) was calculated. Differences of $P < 0.05$ were considered significant.

Results

Of the 5914 medical facilities invited to participate in this survey, 2015 (34%) responded fully or partially to the questions—1923 responded by regular mail and 92 responded by e-mail.

As shown in Fig. 1, of the 2015 survey participants, 1930 (96%) indicated their type of facility—majority were general hospitals with fewer than 200 beds (n = 679, 35%), next were special functioning and regional medical care support hospitals (n = 446, 23%), followed by general hospitals with more than 200 beds (n = 379, 20%). The manufacturer and the magnetic field strength of the MRI scanners are shown in Fig. 2. Of the 2807 scanners in use from October 2017 to September 2018 at the surveyed facilities, 1853 (66%) were 1.5T instruments, 634 (23%) were 3T, and 267 (10%) were < 1.5T scanners.

The average time for 1 MRI examination was 30 min at 965 (49%) of 1987 responding facilities and 20 min in 654 (33%) of them (Fig. 3). During the month of September 2018, 570 of 2015 facilities (28%) performed up to 100 MRI studies, 441 (22%) performed between 100 and 200 examinations, and 312 (15%) performed between 200 and 300 MRI scans. The remaining facilities (n = 692, 34%) performed more than 300 MRI scans in that period (Fig. 4). We found that of 1977 facilities responding to the question regarding the number of MRI-specialized personnel in each facility, 1440 (73%) did not employ MRI-specialized personnel (Fig. 5). No

Table 1 Preparation of MRI safety management and manual

Item	Question[a]	Yes	No	MRI not performed[b]
1	Is there an MRI examination management team composed of the responsible doctor, other doctors, radiological technologists, nurses, etc., in the facility? (n = 2009)	256 (13%)	1753 (87%)	NA
2	Does the MRI examination management team hold meetings on safety management at least once a year? (n = 1880)	170 (9%)	1710 (91%)	NA
3	Does the MRI examination management team regularly give lectures to health-care professionals in the facility? (n = 1876)	357 (19%)	1519 (81%)	NA
4	Do you have a manual for safety management system before MRI inspection in the facility? (n = 1994)	1438 (72%)	556 (28%)	NA
5	Is there an operation manual for sedation of claustrophobic patients and is the cooperation with other department doctors established? (n = 2008)	298 (14%)	1710 (86%)	NA
6	Is there an operation manual that includes a communication system for dealing with magnet quench? (n = 1972)	894 (45%)	1078 (55%)	NA
7	Do you have a manual for dealing with disasters such as earthquakes, floods, and power outages? (n = 1994)	1197 (60%)	797 (40%)	NA
8	Is a system established to check for MRI findings requiring urgent action (such as vascular disorders requiring immediate treatment) and to promptly notify the requesting physician? (n = 1999)	1556 (78%)	443 (22%)	NA
9	Is there an operation manual for MRI examination of pregnant women? (n = 1966)	372 (19%)	666 (34%)	928 (47%)
10	For pediatric patients who need sedation, is an emergency backup system and a system for coordinating with other doctors (anesthesiologists, pediatricians, etc.) prepared and trained? (n = 1969)	201 (10%)	637 (32%)	1131 (58%)
11	Does your facility have an operation manual for patients with implantable medical devices (e.g., pacemakers)? (n = 1976)	640 (33%)	139 (7%)	1197 (60%)
12	Is an operation manual, emergency backup system, and a system to cooperate with doctors (emergency doctors, etc.) in other departments established for allergic reactions and extravasation after use of contrast agents in patients? (n = 2001)	1291 (65%)	423 (21%)	287 (14%)
13	Is there an operation manual and training for ensuring the safety of subjects in an emergency? (n = 1996)	359 (18%)	633 (32%)	1004[c] (50%)
14	As a postmarketing safety measure for gadolinium-contrast agents, have you cooperated with the Pharmacy Department to disseminate important information on postuse cautions in the hospital? (n = 1996)	783 (39%)	925 (46%)	288[d] (15%)
15	As a postmarketing safety measure for drugs used during MRI examinations other than gadolinium-contrast agents (ferucarbotran, scopolamine butyl bromide, glucagon, and manganese chloride), have you cooperated with the Pharmacy Department to disseminate important information about the revision of precautions in the hospital? (n = 1992)	604 (30%)	1030 (52%)	358[e] (18%)

Values are the number of facilities. NA, not available.
[a]The number in parentheses shows the number of facilities that responded to the question item.
[b]MRI examination was not performed for certain patients.
[c]There was an operation manual but no training for ensuring the safety of subjects in an emergency.
[d]The measure was not necessary because contrast-enhanced MRI studies had not been performed.
[e]The measure was not necessary because the MRI examination using drugs other than gadolinium-contrast agents had not been performed.

Table 2 Confirmation at the time of MRI examination request

Item	Question[a]	Yes	No
16	Is there a system to check for contraindicated devices when a doctor requests an examination? (n = 2006)	1658 (83%)	348 (17%)

Values are the number of facilities.
[a]The number in parentheses shows the number of facilities that responded to the question item.

Table 3 Confirmation before MRI examination

Item	Question[a]	Yes	No	MRI not performed[b]
17	Does the patient have sufficient information (such as the risk of metal in the body) necessary for safety management before the MRI examination? (n = 2005)	1962 (98%)	43 (2%)	NA
18	Do you check for the presence of patches in the skin (e.g., thermal patch, thermal wear)? (n = 2007)	1986 (99%)	21 (1%)	NA
19	Have you fully explained and understood how to tell the patient to cancel the test (use of emergency call)? (n = 2007)	1975 (98%)	32 (2%)	NA
20	Do you check for renal function and allergies (allergy to contrast agents, bronchial asthma, etc.) before contrast-enhanced MRI? (n = 2002)	1688 (84%)	22 (1%)	292 (15%)
21	Are measures taken to prevent NSF (checking renal function, eGFR, contrast agent dosage, etc.)? (n = 1999)	1567 (79%)	125 (6%)	307 (15%)
22	Have you checked the following information on the questionnaire for safety management before MRI examination? (Multiple answers are allowed.)			
	Implantable medical device	1977 (98%)		
	Magnetic material in the body	1971 (98%)		
	Tattoo	1897 (94%)		
	History of surgery	1845 (92%)		
	Magnetic material outside the body	1683 (84%)		
	Art makeup	1742 (86%)		
	No confirmation	33(2%)		
23	Have you checked the body for magnetic substances before MRI examination? (Multiple answers are allowed.)			
	Checked with metal detector	890 (44%)		
	Checked with magnetic detector	110 (5%)		
	Checked by doctor's interview	1421 (71%)		
	Checked by paramedical interview	1820 (90%)		
	No confirmation	3 (0.1%)		

Values are the number of facilities. eGFR, estimated glomerular filtration rate; NA, not available; NSF, nephrogenic systemic fibrosis.
[a]The number in parentheses shows the number of facilities that responded to the question item.
[b]The measure was not necessary because contrast-enhanced MRI studies had not been performed.

Table 4 Confirmation during MRI examination

Item	Question[a]	Yes	No
24	Is there an observation of heart rate, blood oxygen level, etc., during an MRI examination for patients who need them? (n = 2004)	1407 (70%)	597 (30%)
25	Are you taking measures against noise? (n = 2004)	1707 (85%)	297 (15%)

Values are the number of facilities.
[a]The number in parentheses shows the number of facilities that responded to the question item.

Table 5 MRI inspection and record

Item	Question[a]	Yes	No
26	Do you record and save examination times and imaging protocols? (n = 1996)	894 (45%)	1102 (55%)
27	Do you have a phantom for quality control of MRI equipment? (n = 2005)	1656 (83%)	349 (17%)
28	Have you checked the operation of the emergency stop function of the bed? (n = 2002)	1164 (58%)	838 (42%)
28	Do you record the temperature and humidity in the MRI room? (n = 2009)	789 (39%)	1220 (61%)
30	Do you record the oxygen concentration in the MRI room? (n = 2004)	730 (36%)	1274 (64%)
31	Have you checked the operation of the oxygen concentration monitor in the MRI room? (n = 2003)	1341 (67%)	662 (33%)
32	Do you record the temperature and humidity in the computer room? (n = 2008)	676 (34%)	1332 (66%)
33	Have you checked the operation of the patient emergency call? (n = 2004)	1721 (86%)	283 (14%)
34	Do you regularly perform maintenance inspections (manufacturer inspections or inspections by qualified personnel other than manufacturers)? (n = 1994)		
	At least once every 3 months	927 (46%)	
	At least once every 6 months	853 (43%)	
	At least once a year	94 (5%)	
	At least once every 2 years	14 (< 1%)	
	No	35 (2%)	
	Others	71 (4%)	
35	Do you record and store the maintenance inspections in item 34? (n = 2006)		
	Yes	1968 (98%)	
	No	4 (< 1 %)	
	No maintenance	34 (2%)	
36	Do you have a maintenance contract for MRI equipment? (n = 1975)		
	Yes	1632 (83%)	
	Inspection only	282 (14%)	
	Others	61 (3%)	
37	Is the MRI machine checked at the start and end of work? (n = 1961)		
	Every day	1663 (85%)	
	Once a week	46 (2%)	
	5 times a week	21 (1%)	
	6 times a week	18 (< 1%)	
	Twice a week	10 (< 1%)	
	Others	12 (< 1%)	
	No	191 (10%)	
38	What are the evaluation items for the phantom scan at the start of the MRI system? (Multiple answers are allowed.)		
	Image artifacts	1175 (58%)	
	Noise	742 (37%)	
	Quantitative image quality	450 (22%)	
	Other items	167 (8%)	
	Unchecked	599 (30%)	

Values are the number of facilities.
[a]The number in parentheses shows the number of facilities that responded to the question item.

Table 6 MRI-related accidents

Item	Question[a]	Yes	No
39	In the past year (October 2017–September 2018), have there been any accidents (major incidents) related to MRI that affect patient health? (n = 1954)	90 (5%)	1864 (95%)
40	In the past year (October 2017–September 2018), have there been any accidents (minor incidents) related to MRI that have not affected the patient's health? (n = 1954)	519 (27%)	1435 (73%)

Values are the number of facilities.
[a]The number in parentheses shows the number of facilities that responded to the question item.

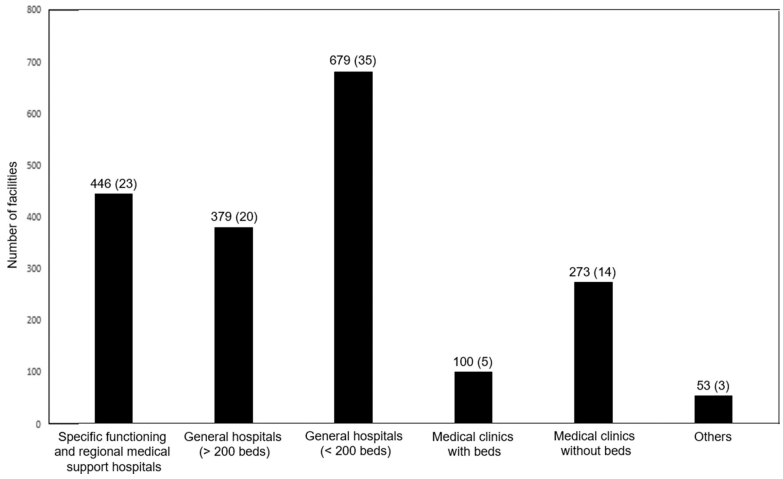


Fig. 1 Type of medical facilities (question 41). Values are the number of facilities. Data in parentheses are percentage.

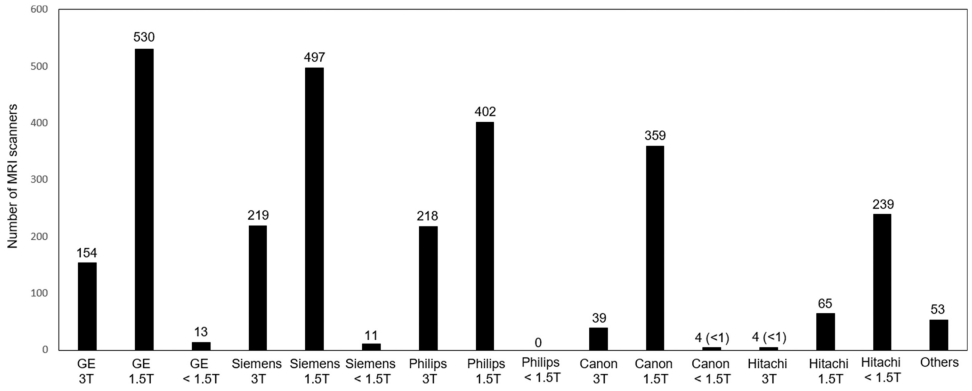


Fig. 2 Manufacturer and magnetic field strength of MRI scanners (multiple answers were allowed) (question 42). Values are the number of MRI scanners. Data in parentheses are percentage.

full-time radiologists involved in MRI protocol instructions, scan interpretation, and face-to-face interactions with patients and/or colleagues were on-site in 1096 (57%) of 1921 responding facilities (Fig. 6); 1185 (60%) of 1971 the facilities did not employ part-time radiologists specialized in MRI issues (Fig. 7).

Tables 1–6 list the answers submitted to the survey questionnaire. Of the 2015 responding facilities, some did not answer specific questions or did not perform MRI in certain patients.

As shown in Table 1, of 2009 responding facilities, only 256 (13%) had an on-site MRI management team and only 170 (9%) of 1880 facilities held management meetings at least once a year. Manuals were available at 1438 (72%) of 1994 facilities that responded to this item; however, 1004 (50%) of 1996 responders did not provide staff training to ensure the safety of patients and personnel in case of an emergency. The availability of manuals for dealing with different situations varied among the institutions. Only 298 (17%) of 1710 facilities provided a manual for the sedation of claustrophobic patients, and 201 (24%) of 838 facilities provided a manual for the management of sedated pediatric patients. Cooperation with the Pharmacy Department to assure the safe handling of gadolinium-contrast agents and of other drugs used during

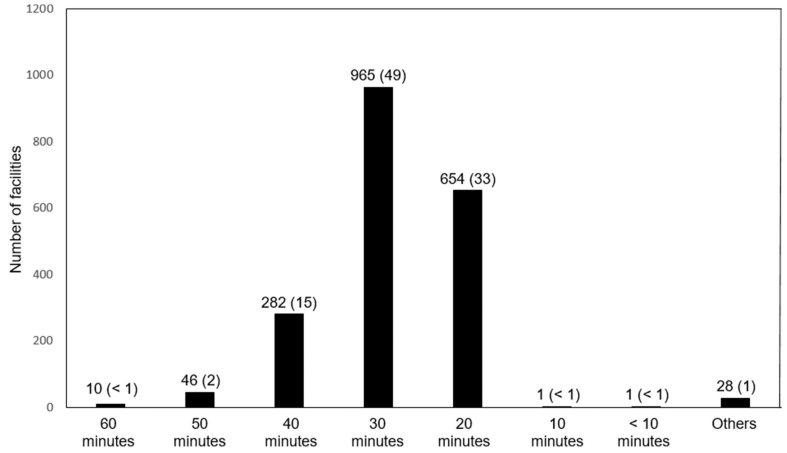


Fig. 3 Average time for 1 MRI examination (question 43). Values are the number of facilities. Data in parentheses are percentage.

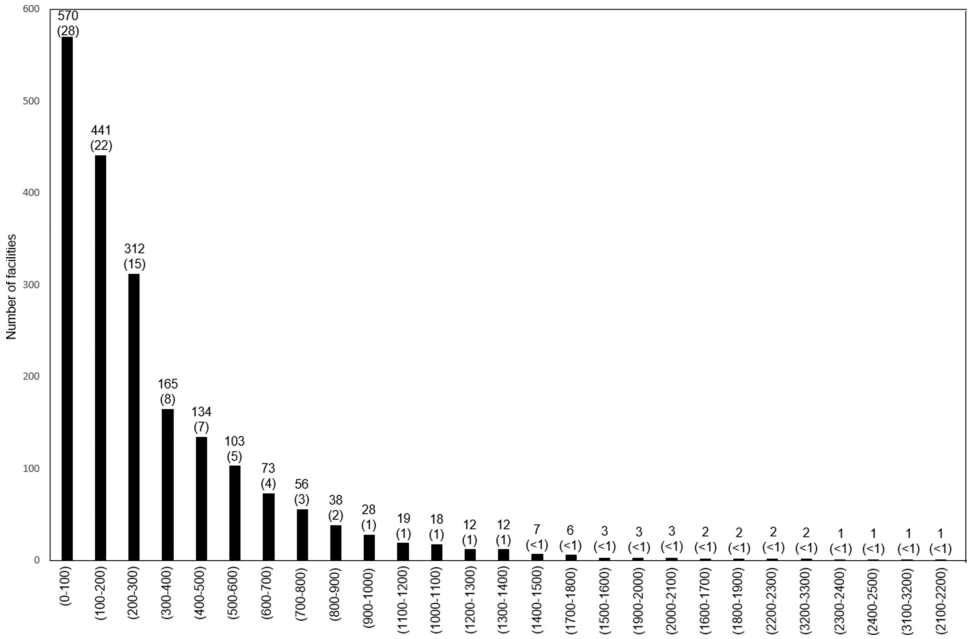


Fig. 4 Total number of MRI examinations during the month of September 2018 (question 44). Values are the total number of MRI examinations. Data in parentheses are percentage.

MRI studies was reported by 783 (46%) of 1708 and by 604 (37%) of 1634 MRI facilities, respectively.

Of 2006 facilities, 1658 (83%) checked their patients for implanted devices before MRI (Table 2). The rate of facilities that addressed the issues with potential effects before MRI examination is shown in Table 3. Of 2004 facilities, 1407 (70%) monitored the heart rate and blood oxygen level during MRI; noise reduction measures were implemented in 1707 of 2004 (85%) facilities (Table 4). The responses to questions related to the maintenance of MRI instruments and MRI records are shown in Table 5. About one-third of facilities kept records of the temperature, humidity, and oxygen concentration in the MRI room, and the temperature and humidity in the computer room. A phantom for quality control of the MRI equipment was present in 1656 (83%) of 2005 facilities. Phantom scans acquired at the start of the MRI system were examined for image artifacts in 1175 (58%) of 2015 facilities.

A summary of MRI-related accidents is shown in Table 6. During the period from October 2017 to September 2018, 90 (5%) of 1954 facilities experienced MRI-related major incidents that affected the patients' health and 519 (27%) minor incidents that did not. Factors that attributed to the occurrence of major and minor incidents are shown in Tables 7 and 8. Among 102 major incidents reported by 90 facilities, 31 (30%) were due to shock or death attributable to the administration of contrast agents; 519 facilities encountered 850

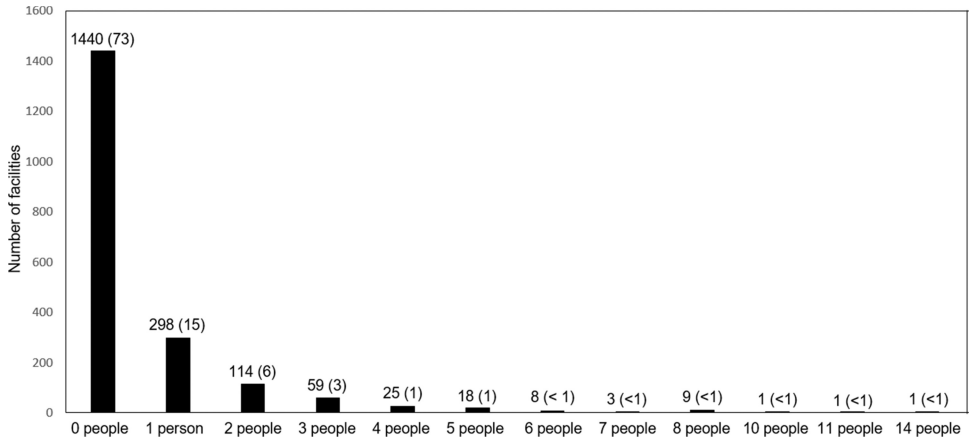


Fig. 5 Number of MRI-specialized personnel in each facility (question 45). Values are the number of facilities. Data in parentheses are percentage.

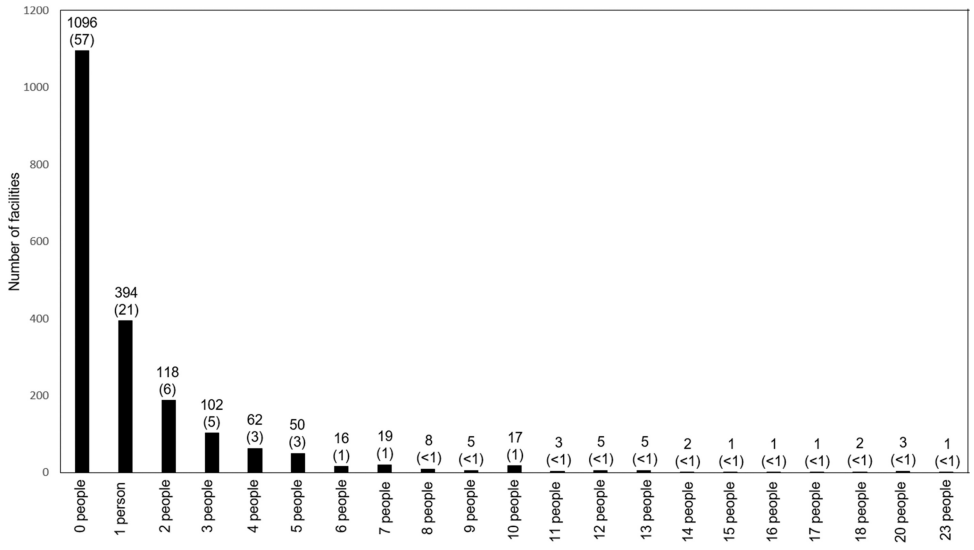


Fig. 6 Number of full-time radiologists involved in MRI protocol instructions, scan interpretation, and face-to-face interactions with patients and/or colleagues in each facility (question 46). Values are the number of facilities. Data in parentheses are percentage.

minor incidents, of which 28% were because of magnetic materials harbored by the patient, which were overlooked.

The automated machine learning platform identified 6 questions that were robust to varying sampling conditions and were strongly associated with major MRI-related incidents (Fig. 8). The median, maximum, and minimum values of the permutation importance for the 6 items are also shown in the figure. Questions with higher permutation importance values are, in descending order, the total number of MRI examinations (question 44), post-marketing safety measures for drugs (question 15), manuals for the management of patients with implanted medical devices (question 11), the number of minor incidents (question 40), checking the body for magnetic substances before MRI examination (question 23), and regular maintenance inspection (question 34). There was a significant positive correlation between the total number of MRI studies and the partial dependence (the risk of major incidents) ($r = 0.8558$, $P < 0.0001$).

To assess the independent impact of individual variables on the occurrence of major incidents, we constructed partial dependence plots for 5 items (Fig. 9). After the total number of MRI studies (question 44), post-marketing safety measures for drugs (question 15) had the second largest impact. The risk ratio of a "no" to a "yes" answer was 1.53 (Fig. 9A). This was followed by a manuals for the management of patients with implanted medical devices (question 11), for which the risk ratio of a "yes" to a "no" answer was 1.17 (Fig. 9B); for the number of minor incidents (question 40), the risk ratio of a "yes" to "no" answer was 1.54 (Fig. 9C). Checking the body for magnetic substances before MRI examination (question 23) had a risk ratio of a "no" to a "yes" response of 2.7 (Fig. 9D). Last, regular maintenance inspections of the MRI equipment (question 34) at least once every 6 months had a risk ratio of a "no" to a "yes" response of 1.79 (Fig. 9E).

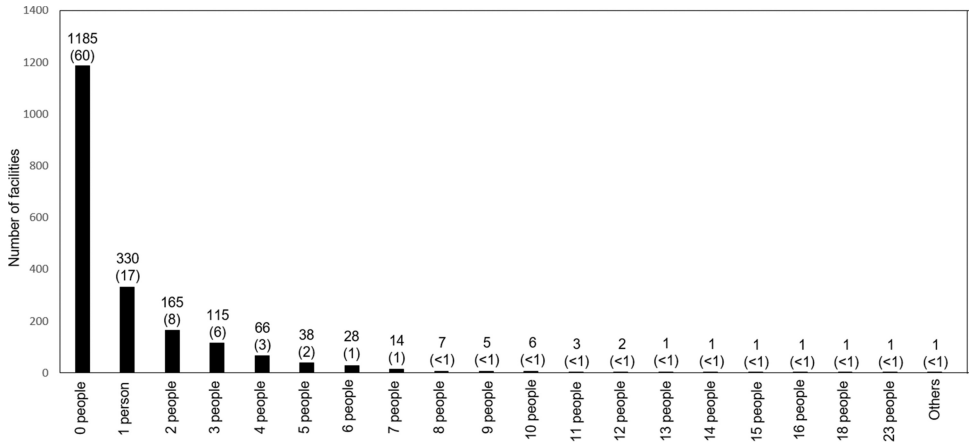
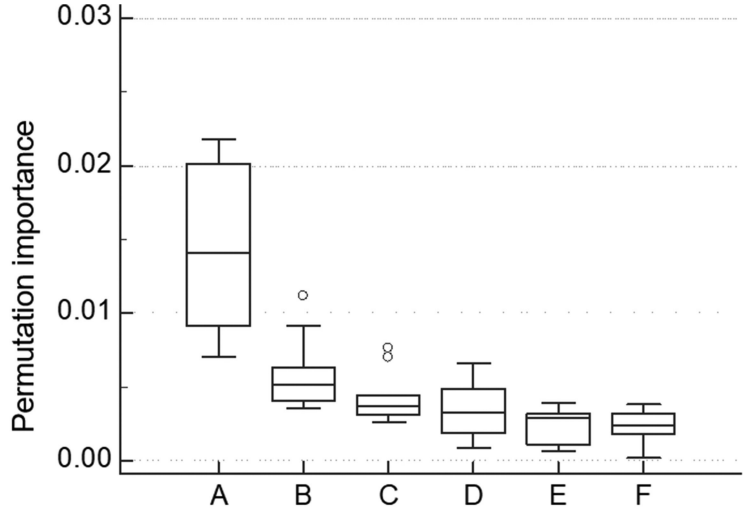


Fig. 7 Number of part-time radiologists specializing in MRI protocol instructions, scan interpretation, and face-to-face interactions with patients and/or colleagues in each facility (question 47). Values are the number of facilities. Data in parentheses are percentage.



Permutation importance	A	B	C	D	E	F
Maximum	0.021873	0.01118	0.007657	0.006541	0.003938	0.003843
Median	0.014103	0.005128	0.003689	0.003271	0.002902	0.002387
Minimum	0.007043	0.003532	0.002555	0.000917	0.000585	0.000198

Fig. 8 The question items associated with major MRI incidents. Box-and-whisker plots show the mean permutation importance for the 6 items (**A**–**F**). The lower and upper hinges of the boxes denote the 25th and 75th percentiles, respectively. The median (50th percentile) of each distribution is indicated by the line. The whiskers on each side denote the 10th and 90th percentiles. The median, maximum, and minimum values of each permutation importance are also shown. (**A**) Question 44 (number of MRI examinations); (**B**) question 15 (postmarketing safety measure for drugs); (**C**) question 11 (manual for implantable medical devices); (**D**) question 40 (minor MRI-related incidents); (**E**) question 23 (body check before MRI examination); and (**F**) question 34 (maintenance inspections).

Discussion

There was a large variation among the responding facilities in the compliance rate with important specific MRI safety items. Highest compliance (99%) was with the requirement to check for transdermal patches (question 18) and the lowest compliance rate (9%) involved the holding of safety management meetings at least once a year (question 2). Only 13% of the respondents had an on-site management team (question 1).

The rates of major and minor incidents related to MRI studies were 5% and 27%, respectively, among facilities responding to this issue. To our knowledge, this is the first study that has presented on a facility-based basis the proportion of major and minor incidents associated with MRI. In 30% of major incidents, the administration of contrast agents was implicated. In a recent systematic review and meta-analysis,[12] it was observed that immediate hypersensitivity reactions occurred in 31 (0.3%) of 14850 administrations (95% confidence interval: 0.2%–0.4%). The majority (90%; 28 of 31) of hypersensitivity reactions were mild; two (6%) were moderate; and one (3%) was severe. Since the study based its evaluations on the number of contrast-enhanced MRI studies rather than on the number of MRI facilities, we were not able to compare the rate of contrast medium–related incidents between their data and ours.

We found that the occurrence of major MRI-related incidents was strongly associated with the number of

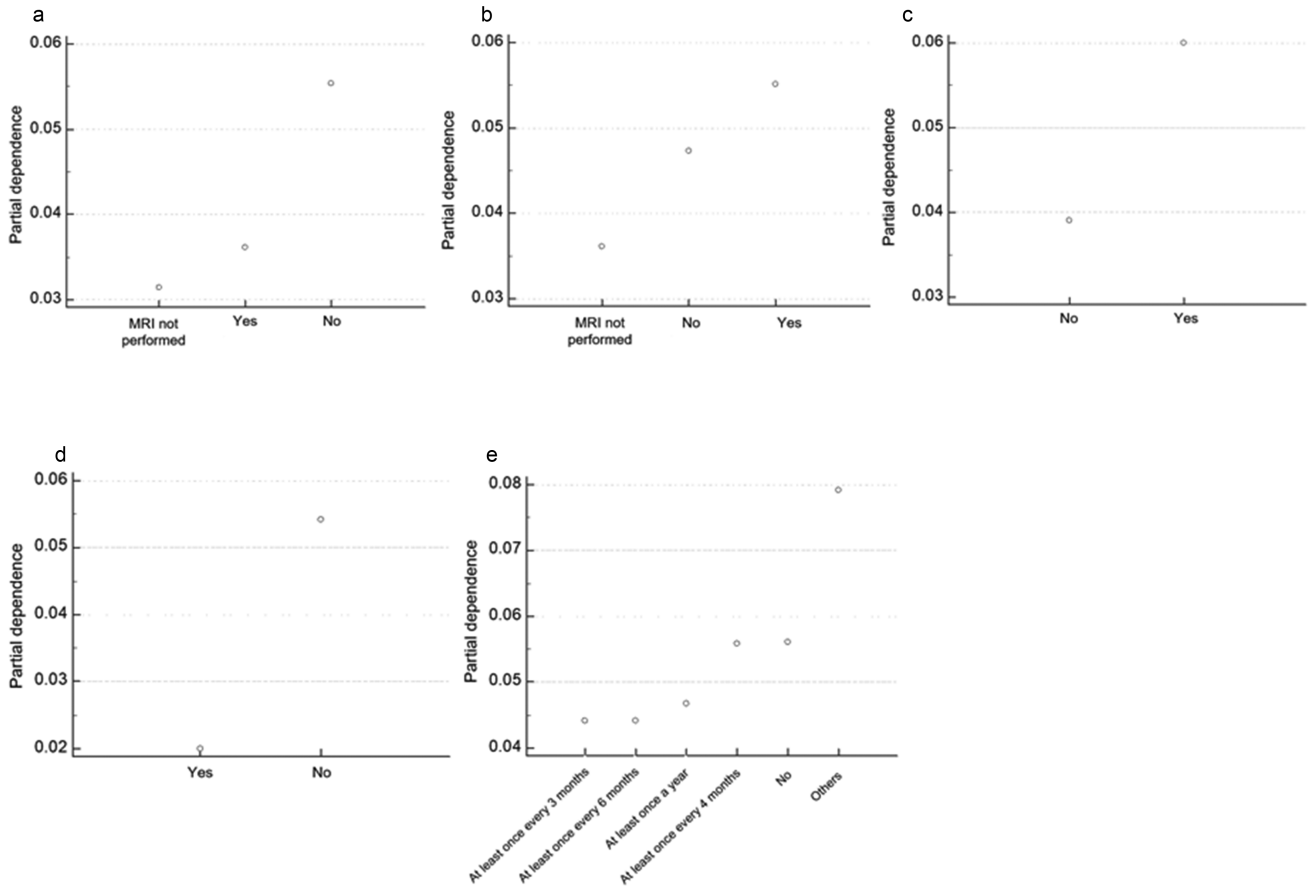


Fig. 9 Partial dependence plots showing independent impact of individual variables on 5 questions.
For question 15 (postmarketing safety measure for drugs) (**A**), "MRI not performed" indicates that the measure is not necessary because MRI examination using drugs other than gadolinium-contrast agents is not performed. The risk ratio of "no" to "yes" was 1.53.
For question 11 (manual for implantable medical devices) (**B**), "MRI not performed" indicates that MRI examination is not performed for patients with implantable medical devices (e.g., pacemakers). The risk ratio of "yes" to "no" was 1.17.
For question 40 (minor MRI-related incidents) (**C**), the risk ratio of "yes" to "no" was 1.54.
For question 23 (body check before MRI examination) (**D**), the risk ratio of "no" to "yes" was 2.7.
For question 34 (maintenance inspections) (**E**), the risk ratio of "no" to "at least once every 6 months" was 1.79 times.

Table 7 Summary of major incidents related to MRI examination (102 cases of 90 facilities)

Contents	No. of cases (%)
Shock or death from contrast agent administration	31 (30)
Burns from tattoos, permanent makeup, etc.	11 (11)
Failure of implantable medical device (pacemaker, etc.)	10 (10)
Tissue damage caused by equipment outside the body (power ankles, etc.)	3 (3)
Others	47 (46)

Table 8 Summary of minor incidents related to MRI examination (850 cases of 519 facilities)

Contents	No. of cases (%)
Overlooking magnetic material in the body	242 (28)
Overlooking equipment outside the body (power ankles, etc.)	146 (17)
Overlooking implantable medical devices (pacemakers, etc.)	127 (15)
Incidents regarding contrast agent administration	96 (11)
Overlooking tattoos, permanent makeup, etc.	22 (3)
Others	217 (26)

MRI studies performed at a facility and that the number of minor incidents was also associated therewith. Our findings indicate that stronger safety standards must be implemented for facilities with a large number of examinations.

To avoid major incidents, manuals, staff training, drug information, and equipment maintenance are of great importance. According to a 2020 report of the Japan Medical Imaging and Radiological Systems Industries Association,[13] the annual estimated number of MR device adsorption incidents in Japan was greater than 100. To reduce this rate, strong safety regulations must be implemented.

Our study revealed that many MRI facilities do not have adequate measures in place to guarantee the safety of MRI. Therefore, we encourage the involvement of academic societies and governmental and nongovernmental agencies. Points to be addressed are as follows:

- The presentation of educational lectures on MRI safety by the Japanese Society for Magnetic Resonance in Medicine
- The promulgation of guidelines by academic societies and government and nongovernment agencies
- The education of all personnel involved in MRI with respect to issues that pertain to MRI safety and the management of accidents
- The granting of more financial support to facilities with strong MRI safety standards by the Central Social Insurance Medical Council and the Ministry of Health, Labour and Welfare.

This study has some limitations. Although we contacted 5914 facilities that performed MRI, only 2015 (34%) responded fully or partially to all questions in the questionnaire. A full participation in the survey could have contributed to a more effective data. In the next questionnaire survey, it is suggested to create a questionnaire with fewer, more targeted questions to encourage higher participation in the survey of MRI facilities.

Conclusion

Among the participating facilities, there was a wide variation in the rate of compliance with the queried MRI safety issues. Nonetheless, our study revealed that overall compliance with safety standards was unsatisfactory. Between October 2017 and September 2018, major MRI-related incidents were reported by 5% of responding facilities and 27% encountered minor incidents. The most common factor implicated in major incidents was related to the administration of contrast agents. The most influential factor involved in major incidents was the total number of MRI studies performed at the facility. In addition to the total number of MRI studies, manuals, staff training, drug information, and equipment maintenance are very important to avoid major incidents. Our findings indicate that for the protection of patients and staff, strong safety standards must be promulgated and implemented and facilities with insufficient standards must be investigated to determine the cause for their inadequate safety management.

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Conflicts of Interest

Ms. Koba is an employee of Varian Medical Systems Inc and Mr. Ijichi is an employee of DataRobot Inc. All data were entirely under the control of the corresponding author. Ms. Koba and Mr. Ijichi provided technical support for the survey and analyses. Dr. Murayama has received a research fund from Canon Medical Systems, Guerbet Japan KK, and Hitachi, Ltd. The other authors have no conflict of interest.

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