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FULL PAPER

Patients with *in-situ* metallic coils and Amplatzer vascular plugs used to treat pulmonary arteriovenous malformations since 1984 can safely undergo magnetic resonance imaging

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Objective: To examine the MRI safety of metallic coils and Amplatzer vascular plugs. Currently, concern regarding MR safety of devices used to treat pulmonary arteriovenous malformations (PAVMs) causes delays in performing emergency MRI in patients presenting with acute neurological symptoms.
Methods: A retrospective audit was performed on all patients who underwent PAVM embolization at Hammersmith Hospital, London UK between 1984 and 2017. Outcomes of all MRI studies performed at our institution were recorded. In addition, known outcomes of all known MRI studies performed on patients treated with the earliest steel coils (1984–1995) were recorded.
Results: At our institution, 20 patients underwent 1.5 T MRI after the insertion of 100 steel coils (15.5 – 28.6, median 22 years later), 140 coils designated MR-conditional (0.42 – 12.7, median 9.3 years later), and 54 MRI-conditional Amplatzer vascular plugs (0.17 – 8.0, median 0.75 years later), many in combination. The majority of scans were for cerebral indications, but other body regions scanned included spinal, thoracic, and pelvic regions. No adverse events were reported. Similarly, there were no adverse events in any MR scan known to have been performed in other institutions in seven further patients treated with the earliest steel coils (1984–1995). Again, the majority of scans were for cerebral indications.
Conclusion: The findings demonstrate MR safety at 1.5 T of all PAVM embolization devices inserted in a main UK centre since inception in 1984.
Advances in knowledge: MRI of patients who have had PAVMs treated by embolization can be implemented without contacting specialist pulmonary arteriovenous malformation treatment centres for approval.

INTRODUCTION

Great care is taken to ensure that any patient referred for an MRI study does not have an implanted metallic device that might cause harm due to movement or excessive heating during the examination. The American Society for Testing and Materials (ASTM[1]) categorizes all devices into MRI safe, conditional or unsafe: Any metallic implanted device has ferromagnetic potential, so is categorized as conditional or unsafe. Being MRI conditional is defined by the ASTM[1] as: "an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Conditions that define the MR environment include static magnetic field strength, radiofrequency fields, specific absorption rate and other factors. For MR conditional items, the item labelling includes results of testing sufficient to characterize the behaviour of the item in the MR environment."[1]

Firm data are available regarding the safety or otherwise of many commonly used implants. Imaging staff have easy access to these reports. In contrast, it is difficult to find safety data for less frequently encountered devices. Sources of expert advice then need to be identified and contacted, with inevitable delays that will often result in a scheduled MR study being postponed, or even cancelled.

This is a particular problem for patients with pulmonary arteriovenous malformations (PAVMs[2]). PAVMs provide

direct communications between pulmonary arteries and pulmonary veins, thereby allowing a right-to-left shunt, and are clearly distinguishable radiologically from other vascular and non-vascular "mimics."[3] Current estimates are that PAVMs may affect as many as 1 in 2600 people,[4] though most are asymptomatic and remain undiagnosed.[2] When a diagnosis of PAVM(s) is made, treatment is recommended to reduce the associated risks of stroke and brain abscess due to paradoxical embolization through the intrapulmonary arteriovenous communications.[2,4–7] Since the mid-1980s, the treatment of choice has been embolization therapy using permanent metallic devices.

Thus where PAVM(s) have already been treated, permanent metallic devices will have been inserted into the dilated feeding arteries to PAVMs, leading to sac obliteration, and restoration of normal calibre pulmonary arteries.[3–17]

The problem if such patients subsequently require an MR scan, is that early PAVM embolization devices (pre-1996)[8–10] were manufactured prior to the advent of routine clinical MRI, and later devices are still classified as "MR conditional" (*e.g.* MReye coils,[11,12] Amplatzer Vascular Plugs).[14,15] There is one published report on the MR tolerance of intrathoracic stainless steel coils,[18] but the indications did not include PAVM embolization. PubMed searches using the terms ["pulmonary" or "thoracic"], "MR" and "embolization" currently identify no publications assessing MR-safety of stainless steel embolization coils. Further searches retrieved sites such as MRIsafety.com, where there are comments that for most coils, filters, stents and grafts that have been tested, it is unlikely that these implants would become moved or dislodged as a result of exposure to MR systems operating at 1.5-Tesla or less.[19] However, all PAVM embolization devices (stainless steel and platinum-based) are listed as MRI "conditional."[19]

Patients who have had PAVMs embolized may require urgent or emergency MRI in a variety of clinical settings, as for any member of the general population. Many also remain at risk of complications directly attributable to PAVMs that were not amenable to embolization because of their small size at the time of their original treatment.[3,10–12,14] Although this risk is lower than before treatment, it is not negligible.[20,21] For example, PAVM patients frequently require urgent cerebral MRI to investigate the cause of acute neurological symptoms and distinguish between cerebral abscess, ischaemic, and haemorrhagic pathologies. Delays in MR diagnosis and subsequent management can have life-changing consequences, particularly for patients with a cerebral abscess where prompt treatment is associated with better outcomes.[22] In a recent series of 37 consecutive patients with PAVMs experiencing a cerebral abscess, more than 50% of surviving patients were left with life-changing disability.[21]

Similarly, for PAVM patients presenting clinically with an ischaemic stroke (affecting 61/497 (12.3%) of one recent series[23]), delays in excluding haemorrhage can delay institution of appropriate early treatments for ischaemic strokes.[24] The latter concern may be heightened where PAVMs are recognised to be due to hereditary haemorrhagic telangiectasia (HHT), an inherited condition that results in cerebral vascular malformations in approximately 10% of cases.[25,26] The risk of haemorrhage from cerebral vascular malformations is well recognised, and commonly (though incorrectly[27]) emphasised for patients with HHT as their top stroke risk.[28,29]

Our own experience reflects that the presence of PAVM embolization devices inserted at our institution was leading to delays in other institutions performing MR scans, while safety data were sought. We presume this is due to the recognition that PAVM embolization results in the placement of embolization devices effectively within mobile pulmonary parenchyma and often in close proximity to alveoli where the theoretical risk of movement and heating is greater than for devices placed elsewhere.

The goal of this study was to report the tolerance of MR scans in a large cohort of patients with PAVM embolization devices *in situ* within lung parenchyma at the time of MRI.

METHODS AND MATERIALS

Literature searches

PubMed and Google searches were performed using the search terms ["pulmonary" and "embolization" and "MR"]; ["pulmonary" and "arteriovenous" and "MR"] and ["thoracic" and "embolization" and "MR"], most recently on 26 July 2018.

Case reviews

Embolization was performed at Hammersmith Hospital (now part of Imperial College Healthcare NHS Trust), according to clinical need, as reported elsewhere.[5,6,8,13,14] Prior to the 1996 introduction of MR-conditional embolization coils (Mreye®, William Cook, Europe), embolization was performed using steel coils that were not designated as being safe in patients undergoing MRI. Between 1984 and 1995, 136 embolization procedures using these stainless steel coils (William Cook), were performed in 99 patients at Hammersmith Hospital, in a period when there was no specific manufacturer labelling of embolization devices relating to MR safety (William Cook Europe).

MR-conditional coils were released in 1996 (Mreye®, William Cook Europe[11]), and were used for all PAVM embolization procedures performed from this date until September 2006. MR-conditional Amplatzer vascular plugs (St. Jude Medical) were used from September 2006 with additional Mreye® coils and platinum microcoils[30,31], in some patients.

For the purposes of this study, the case records of all patients known to have undergone MRI between May 1999 and December 2017, were evaluated to record the exact number, type, and insertion date of PAVM embolization devices. Primary medical records of patients on our 34 year PAVM database were reviewed. This included paper case notes from 1984, separately filed clinic letters and angiography suite records from 1984 (audited as part of earlier studies), in addition to the electronic PACS system in operation since 1996.

MRI studies

From 1999, MRI was performed for a variety of indications at patients' local hospitals, most after directly seeking confirmation from us. Between 1999 and 2005, because of the limited safety data available at that time, CT was advised in those patients in whom coils that were not designated as being MR-compatible had been used, when the indication for MRI was not considered sufficiently urgent to warrant the potential risk.

Patients who needed emergency brain imaging in our own institution underwent MRI when the potential risk was considered justified; initially these studies were performed with medical team members in the scanning unit to manage any complication that might occur. Similar advice was provided to external units between 1999 and 2005, while experience was accruing.

Since 2005, the advice has been that MRI is tolerated by all patients in whom PAVM embolization has been performed since 1984 regardless of the embolic agent that has been used so long as a period of at least 6 weeks has passed since the most recent embolization procedure.

Notes review

Ethics approval was from the Hammersmith, Queen Charlotte's, Chelsea, and Acton Hospital Research Ethics Committee (LREC 2000/5764: "Case Notes Review: Hammersmith Hospital patients with pulmonary arteriovenous malformations and hereditary haemorrhagic telangiectasia (HHT)".) The ethics committee approved the review of the case notes for research purposes without seeking individual consents.

Primary medical records of patients on our 34 year PAVM database were reviewed. This included paper case notes from 1984, separately-filed clinic letters and angiography suite records from 1984 (audited as part of earlier studies), in addition to the electronic PACS system in operation since 1996.

Data analyses

Data were analyzed using STATA IC v. 13 (StataCorp. 2013. *Stata Statistical Software: Release 13*. College Station, TX: StataCorp LP) and Graph Pad Prism version 7.03 Graph Pad Prism for Windows, Graph Pad Software, San Diego, California USA, www.graphpad.com.

RESULTS

The scale of the problem

At Hammersmith Hospital we receive multiple requests each year on the MR-safety of PAVM embolization devices. Despite the 2016 publication of Slesnick et al,[18] ten requests were received in 2017 and 2018 requests continue at a similar rate per month. Notably, almost all of these concern embolization devices that were inserted after 1996 and were designated to be MR-conditional in the original discharge letter and angiogram report. However, the information available to relevant radiological staff was clearly not considered sufficient to allow the scans to proceed.

We are aware of two cases in the last 12 months where a delay in MRI led to delayed neurosurgery for cerebral abscesses. Neither patient has made a full recovery.

Steel coil PAVM treatments and scan tolerance

Table 1 lists the number of steel coils and scan details of 11 patients scanned at an interval of 5–29 years after insertion of stainless steel coils. Indications varied, and included spinal and pelvic scans, but were predominantly for cerebral indications. The scans were performed either at the patients' own institutions, or at our institution (Hammersmith Hospital) as noted.

There were no reported MRI-related complications at the time, or from the patients or their family members who subsequently attended our services for review.

Table 1. Patients with pre-1996 steel coils embolization devices known to have had an MR scan

	Year of MR scan	Indication	Emergency, elective or screening MR scan	Steel coils inserted	Number of steel coils	Advice provided by us?
#1	1999*	Cerebral	Emergency	1994	12	"Agree require. Use lowest possible magnetic strength scan to obtain data; have chest drain pack ready, and watch clinically for possible pulmonary haemorrhage"
#2	2002	Cerebral	Emergency	1987–1989	24	In-house
#3	2003	Spinal	Elective	1987	>2	None requested- our team were not aware the scan was taking place
#4	2005*	Cerebral	Emergency	1992, 1993	3	"Benefit outweighs risk. Suggest consent to include possibility of pneumothorax and chest drain- ensure Respiratory SpR or Consultant in scanner suite at time"
#5–8	2008–2014	Cerebral	3 Elective, one emergency	1987–1992	>21	Confirmed MR-compatibility where requested
#9	2009	Cerebral	Emergency	1990–1995	13	In-house
#10	2011	Cerebral	Elective	1988–1996	48	In-house
#11	2013	Cerebral	Elective	1984–1989	15	In-house

Table 2. Summary of devices and time present

			Number per patient		Time present (years)	
PAVM embolization device *in situ* at time of MR scan	**Number**	**Years inserted**	**Median**	**Range**	**Median**	**Range**
Steel coils	100	1984–1996	19.5	13–48	22	15.5–28.6
MR-conditional MReye® coils	140	1996–2017*	7	2–40	9.3	0.42–12.7
MR-conditional Amplatzer vascular plugs	54	2006–2017*	3	1–4	0.75	0.17–8.0

PAVM embolization devices present in 20 different patients at the time of an MR scan at our institution between 2000–2017. No balloons were used in this series, and by chance, no MRI studies were performed in patients who had been treated with platinum microcoils. * Continue in use. MRI was performed for investigation of neurological, spinal or thoracic symptoms, or for screening purposes (cerebral, or spinal in pregnancy.[32]

All device PAVM treatments and MRI tolerance

At our institution most MR scans performed in patients with previously embolized PAVMs were for cerebral indications, but one patient had a thoracic MR scan performed the year after embolization.

In total, 20 patients had 100 steel coils scanned at an interval of 15.5–28.6 (median 22) years; 140 coils designated MR-conditional scanned at an interval of 0.42–12.7 (median 9.3) years, and 54 MRI-conditional Amplatzer vascular plugs (AVPs) scanned 0.17–8.0 (median 0.75) years after insertion. 10 patients had one or more AVP1s *in situ* at the time of the MR scan, and 10 had AVP4s *in situ* .

Details of the cerebral MR scan methodology are reported elsewhere[30] but included T2- and T_1 weighted imaging, fluid-attenuated inversion recovery imaging, diffusion weighted imaging, susceptibility weighted imaging; gradient echo T_2*; gadolinium (contrast) enhanced imaging and time-of-flight angiography. Scans were performed using 1.5T devices.

No MRI-related complications were reported in this cohort.

To emphasize the range of PAVM embolization devices that were tolerated without ill-effect, Table 2 details by device type, the devices that were present in the lungs of patients undergoing MRI at our institution (Hammersmith Hospital). No balloons were used in this series. The data therefore relate to patients whose PAVMs were treated with either steel coils inserted between 1984 and 1996, MR-conditional MReye® coils inserted since 1996, or MR-conditional Amplatzer vascular plugs inserted since 2017.

To further emphasize the totality of devices that were tolerated without ill-effect, Table 3 details by patient the devices that were present in the lungs of patients undergoing MRI at our institution (Hammersmith Hospital). This illustrates not only the devices present at the time of complication-free MRI, but also the combinations of devices present. Overall, 10 cases had AVP1s in *situ* at time of MR scan, 10 cases had AVP 4 s *in situ,* 11 had MReye® coils, 11 had steel coils and 1 patient had platinum microcoils *in situ.*

DISCUSSION

This study demonstrates that cerebral, thoracic, pelvic and spinal 1.5 T MRI can safely be performed in patients who have undergone PAVM embolization since 1984 using devices that are commonly perceived as being MR-incompatible, despite the majority used since 1996 now being labelled as MR-conditional.

The use of MRI to assess PAVM recanalization after embolization using platinum microcoils has been described[31,33] but there do not appear to be any studies on PAVM embolization device MR-safety when steel coils have been used. The current study emphasises that the apparent current default "Do not scan until more information is obtained" approach will result in detrimental delays in emergency situations.

Cook® Stainless steel embolization coils had no designated MRI-safety label for years after their release. In 2011, Cook designated these coils as MRI-unsafe due to their ferromagnetic properties but after further testing by the manufacturer, the coils were designated as MR-conditional in 2012.[34] In 2016, Slesnik et al[18] reported the MR-safety of stainless steel coils in a large group of children in whom these devices had been used for a variety of extrapulmonary thoracic embolization procedures. Although these findings are reassuring, they cannot be extrapolated to coils within the lungs where there is theoretically a greater likelihood of movement during MRI with the risk of local lung parenchymal

Table 3. Multiple device types *in situ* in same patient

Combination	**Number of patients**
Stainless steel coils only	0
MR-conditional MReye® coils only	4
Amplatzer vascular plugs only	9
Platinum microcoils only	0
Stainless steel coils + MR-conditional MReye® coils only	2
Stainless steel coils + Amplatzer Vascular Plugs	0
MR-conditional MReye® coils + Amplatzer Vascular Plugs	2
MR-conditional MReye® coils + Amplatzer Vascular Plugs + Platinum microcoils	1
Stainless steel coils + MR-conditional MReye® coils + Amplatzer Vascular Plugs	2

Combinations of devices present in 20 different patients at the time of an MR scan at our institution between 2000–2017

damage resulting in alveolar haemorrhage and/or pneumothorax. Furthermore, the number of requests to us for advice on MR compatibility was higher after publication of[18] than in any of the preceding 3 years, indicating this paper was either not being accessed, or not being interpreted by relevant radiology units to allow scans to proceed.

In practice, none of the devices inserted at our institution (Hammersmith Hospital) were considered an absolute contraindication to MRI where required for emergency indications. Although there are theoretical risks, these were not observed in clinical practice. As a result of this clinical experience with tolerability of the earliest PAVM embolization devices derived from such scans, since 2005 no cautionary comments were issued by us.

CONCLUSION

Patients with PAVMs who have undergone embolization using stainless steel coils and/or Amplatzer vascular plugs can safely undergo 1.5 T MRI which should not be delayed in emergency situations.

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