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Agence canadienne des médicaments et des technologies de la santé

CADTH Optimal Use Report

Pilot Project

1.5 Tesla Magnetic Resonance Imaging Scanners Compared with 3.0 Tesla Magnetic Resonance Imaging Scanners: Systematic Review of Clinical Effectiveness

May 2011

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Canadian Agency for Drugs and Technologies in Health

1.5 Tesla Magnetic Resonance Imaging Scanners Compared with 3.0 Tesla Magnetic Resonance Imaging Scanners: Systematic Review of Clinical Effectiveness

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May 2011

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This report is a review of existing literature, studies, materials, and other information and documentation (collectively the "source documentation") that are available to CADTH. The accuracy of the contents of the source documentation on which this report is based is not warranted, assured, or represented in any way by CADTH, and CADTH does not assume responsibility for the quality, propriety, inaccuracies, or reasonableness of any statements, information, or conclusions contained in the source documentation.

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Authorship

Ron Wood, Vicki Foerster, Ken Bassett, Leonard Tong, and Carolyn Spry participated in planning and reviewing the project. Ron Wood led the authoring team and was the key liaison between ProMed and CADTH. Ron Wood also wrote the sections on MRI utilization, and contributed to the cost table. Vicki Foerster and Ken Bassett were responsible for the evaluative framework, study selection, data extraction, evidence tables, and drafting substantial parts of the systematic review. Leonard Tong was responsible for reviewing the original equipment manufacturer information, cost table, pros and cons of 1.5 T MRI and 3.0 T MRI table, as well as describing MRI installation. Carolyn Spry designed and performed the literature search, wrote material in the report related to literature searching, and verified bibliographic references.

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Conflicts of Interest

None declared.

EXECUTIVE SUMMARY

Issue

Medical technologies are continually changing and magnetic resonance imaging (MRI) is no exception, where increasing the magnet strength has produced more sophisticated device capabilities. A systematic review of the evidence comparing the clinical applications of 1.5 Tesla (T) MRI with those of 3.0 T MRI aims to provide health care decision makers such as government purchasers, health care planners, and clinicians with information about the clinical effectiveness and institutional efficiency of the 1.5 T MRI and 3.0 T MRI.

Research Questions

The purpose of this review is to evaluate the differences between 1.5 T MRI and 3.0 T MRI scanners. The research questions are:

1. What are the clinical benefits, limitations, and safety considerations for imaging with a 1.5 T MRI scanner compared with a 3.0 T MRI scanner?
2. What are the service delivery, personnel, and structural (renovation, installation) differences between a 1.5 T MRI scanner and a 3.0 T MRI scanner?

Methods

A literature search was conducted on health technology assessment (HTA) resources, including MEDLINE, EMBASE, CINAHL, PubMed, The Cochrane Library (Issue 11, 2010), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English or French language articles that were published between January 1, 2005 and November 29, 2010. Regular alerts are current to April 27, 2011. Methodological filters were applied to limit the retrieval of articles on 1.5 T MRI or 3.0 T MRI systems to HTAs, systematic reviews, and meta-analyses. No filters were applied to limit the retrieval by study type for articles that compared 1.5 T MRI and 3.0 T MRI systems. Two independent reviewers screened articles using predefined criteria.

To answer the research question on clinical benefit, limitations, and safety, a systematic review was conducted. The clinical effectiveness of MRI scanners was evaluated by assessing clinically meaningful outcomes including effect on diagnosis, clinical management decisions, or patient outcomes as reported in comparative studies of 1.5 T MRI and of 3.0 T MRI. The outcomes specific to technical aspects of imaging such as image quality were not considered. The included studies involved at least 20 patients who were individually assessed using 1.5 T MRI and 3.0 T MRI within one week for acute conditions and within one month for chronic conditions.

To answer the research question on service delivery, personnel, and structural differences, information was gathered from the Canadian Institute for Health Information (CIHI), peer-reviewed literature, vendors, web-based resources, and experts. In addition, a survey of the five MRI vendors in Canada was undertaken.

Clinical Review

Twenty-five studies met the inclusion criteria for the systematic review. The six neurology studies, four cerebrovascular studies, three cardiac studies, one renal study, three musculoskeletal studies, and eight oncology studies were assessed. All studies were prospective and observational, assessing between 20 patients and 65 patients who received repeat testing with 1.5 T MRI and with 3.0 T MRI within one week for acute conditions and one month for chronic conditions. Two or more interpreters (generally radiologists), usually blinded to magnet size and clinical scenario, assessed the images using standardized quantitative and qualitative measures. Findings were recorded independently and then compared, or agreement on the findings was achieved by consensus.

In some cases, the diagnostic test parameters were assessed by comparing the radiological diagnosis with gold standard test results (for example, pathological examination of lesions) for 1.5 T MRI and 3.0 T MRI. The clinical test parameters were then calculated as sensitivity, specificity, positive predictive value, and negative predictive value. Some studies showed a statistically significantly higher sensitivity when using a 3.0 T magnet for smaller and more isolated lesions but the clinical significance of this increased detail is unclear.

No studies assessed whether the differences in diagnostic test parameters produced differences in clinical management or patient outcomes, although several studies acknowledged that to draw clinically valid conclusions, studies must be larger, enrol a broader spectrum of patients, and include more extensive patient follow-up.

Regarding implanted medical devices, more than 1,800 objects have been tested using 1.5 T MRI scanners and approximately 600 objects using 3.0 T MRI scanners. Other safety concerns relate to the higher magnet strength of 3.0 T MRI compared with 1.5 T MRI; including that: ferromagnetic objects near the device will exhibit an abrupt pull from a 3.0 T magnet compared to a gradual pull with 1.5 T, the heating potential with increased magnet strength may increase risk of burns, and the noise level of 3.0 T MRI scanning is higher than that of 1.5 T MRI.

Regarding limitations, there is a lack of evidence linking MRI's technical findings to clinically meaningful outcomes. Only those studies meeting the selection criteria were included in the systematic review. As a result, several MRI indications were excluded; for example, brain tumours, epilepsy, and knee pathology. In addition, no studies of pediatric populations met the inclusion criteria. Studies tended to be small, generally with 20 patients to 30 patients enrolled. Another issue is the increasing sophistication and changing performance of MRI devices. Some included studies were conducted in 2003 when 3.0 T MRI was in the early stages of introduction. Current 1.5 T MRI and 3.0 T MRI devices would now perform differently.

Each year, CIHI publishes data on public and private high technology installations in Canada, including MRI. January 2009 data[1] show 212 MRI installations, of which eight were 3.0 T (in Alberta, Ontario, and Quebec). The national mean number of examinations per MRI scanner was 5,750. For 2008 to 2009 use, the national mean was 41.4 MRI examinations per 1,000 people, which is below that of the countries in the Organisation for Economic Co-operation and Development, where a mean of 48.5 examinations per 1,000 people was reported.

Conclusions

The evidence on clinical test parameters (for example, number of lesions) shows that 3.0 T MRI, in general, performs as well as or better than 1.5 T MRI for the studies included in this review. Study design is, however, limited by factors such as design and sample size. The evidence on diagnostic and technical test parameters does not indicate whether patients will receive different clinical management or experience different health outcomes. That is, the relative clinical effectiveness of 3.0 T MRI compared with 1.5 T MRI cannot be determined. There is a lack of evidence on the safety of using 3.0 T MRI with implanted devices. Other factors to consider with a 3.0 T MRI is the extent to which a facility with a 1.5 T MRI requires renovation to house a 3.0 T MRI, the experience of staff, the need for research applications, and the need for current and future clinical applications.

ABBREVIATIONS

CAD	coronary artery disease
CIHI	Canadian Institute for Health Information
CNR	contrast-to-noise ratio
CT	computed tomography
HTA	health technology assessment
HTIS	Health Technology Information Service
ICA	intracerebral aneurysm
MI	myocardial infarction
MRI	magnetic resonance imaging
MS	multiple sclerosis
NPV	negative predictive value
OEM	original equipment manufacturer
PPV	positive predictive value
RAS	renal artery stenosis
SNR	signal-to-noise ratio
T	Tesla
TMJ	temporomandibular joint

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1 INTRODUCTION

1.1 Background and Setting in Canada

Medical technologies are continually changing and diagnostic imaging is no exception. This report focuses on magnetic resonance imaging (MRI), where increasing magnet strength has produced more sophisticated device capabilities. Most installed clinical MRI scanners have been built around a 1.5 Tesla (T) magnet, but newer devices include magnets of greater strength at 3.0 T and at 7.0 T. A glossary[2] of MRI terminology is available.

MRI is useful in the investigation of many clinical conditions. One co-author noted that common disorders for MRI scanning at some Vancouver hospitals include those shown in Table 1 (LT, unpublished observations, 2011). More information is also available.[3,4]

Table 1: Common Conditions Investigated Using an MRI Scanner

Site	Condition
Head	Brain tumours (including pituitary and acoustic neuromas), follow-up brain surgery
Spine	Tumours, acute cord compression, myelopathy, spinal canal stenosis
Musculoskeletal system	Knee (internal derangement, torn anterior cruciate ligament, torn meniscus); shoulder (rotator cuff tear)

The increasing magnet strength is accompanied by increasing costs of purchase, installation, and operation. There are also concerns about safety as a number of implanted devices deemed to be safe with 1.5 T MRI scanning are not yet deemed safe with 3.0 T scanning.[5] There is also uncertainty as to whether the stronger 3.0 T MRI magnet is superior to a 1.5 T magnet in clinical applications and how this affects outcomes for patients.

1.2 Overview of MRI Technology

An MRI scanner emits a strong magnetic field that aligns the nucleic spin orientation of hydrogen atoms at a low energy state in a patient. To manipulate the nucleic spin of hydrogen atoms in another direction (to a higher energy state), MRI emits a radiofrequency into an area in the body. The MRI then captures the energy that is released by hydrogen-bound molecules transitioning from a high to a low energy state. This exchange of energy between spin states is called resonance, hence resonance imaging.

A resonance frequency receiver coil detects the energy emitted from the hydrogen atoms, and a computer displays the different resonance characteristics of various tissue types as an image. The image shows body tissues in various shades of grey.[6] The amount of the signal (the strength of the energy emission from induced hydrogen atoms) that is used to compose an image is proportional to the magnetic field strength of the scanner. Signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR), spatial resolution, and temporal resolution are the standard references that are used to judge MRI image quality. The features of 1.5 T MRI and 3.0 T MRI are summarized in Appendix 1.

2 ISSUE

1.5 T MRI scanners are in common use, but increasingly powerful magnet strengths (for example, 3.0 T) are available. The clinical benefits of using the increased magnet strengths are of interest. This systematic review of scientific evidence comparing the clinical application of 1.5 T MRI to 3.0 T MRI provides government purchasers, health care decision makers such as health care planners, and clinicians with information about the clinical effectiveness and institutional efficiency of 3.0 T MRI scanning compared with conventional 1.5 T MRI scanning.

3 RESEARCH QUESTIONS

The purpose of this review is to evaluate the differences between 1.5 T MRI and 3.0 T MRI scanners. The research questions are:

1. What are the clinical benefits, limitations, and safety considerations for imaging with a 1.5 T MRI scanner compared with a 3.0 T MRI scanner?
2. What are the service delivery, personnel, and structural (renovation, installation) differences between a 1.5 T MRI scanner and a 3.0 T MRI scanner?

Supplemental information was gathered on 1.5 T MRI and 3.0 T MRI for guidelines, construction and installation, costs, and safety. Summaries of this information can be found at the end of this report.

4 CLINICAL REVIEW

This review involved five people (CS, KB, VF, LT and RW). Literature search strategies and searches were completed by CS. KB and VF selected and assessed the primary studies to address the first research question of the systematic review. RW and LT provided technology expertise in completing report sections related to the second research question on health services.

4.1 Methods

4.1.1 Evaluative framework

The ideal research study would randomize patients to receive a program of care involving 1.5 T MRI or 3.0 T MRI testing with clinically meaningful (instead of purely technical) outcomes. This design would address the differences between 1.5 T MRI and 3.0 T MRI in relative contributions to their effects on diagnosis, clinical management, or clinical (health or patient) outcomes. It would also show whether improved imaging spared patients with valid negative findings from unnecessary treatment and the inevitable complications, inconvenience, and expense. This programmatic evaluation could be conducted less rigorously by comparing similar institutions or regions, one with 1.5 T MRI and the other with 3.0 T MRI technology. In accordance with this paradigm, the authors of the systematic review sought evidence that alternative MRI technology (1.5 T or 3.0 T), at a minimum, affected diagnosis or changes in

clinical management. A change in clinical management is the second step in the appraisal of the clinical effectiveness of testing technology (Figure 1). This step leads to, but does not directly provide, evidence on final clinical outcomes (for example, subsequent morbidity and mortality).

FIGURE 1: Three-step framework to explore clinical effectiveness

Accepting evidence on impact on diagnoses or clinical management decisions (as opposed to clinical outcomes) is necessary for assessing imaging technology where there seems to be limited interest in or funding for definitive clinical studies. Therefore, studies were examined for evidence that 3.0 T MRI findings compared to 1.5 T MRI findings had an impact on physician behaviour (enabled physicians to sort patients into risk groups for future events and to treat them according to patient risk status).

Without direct randomized controlled trial evidence of the impact of using MRI on clinical management and clinical outcomes, this systematic review sought evidence related to clinical test performance. Measuring clinical test performance depends on a reliable correlation with a gold standard test for a condition. For example, cancer diagnosis depends on the histological examination of tissue and cancer staging depends on the findings at surgical intervention. For diseases such as multiple sclerosis (MS), gold standard diagnosis only becomes apparent over time and with overt neurological manifestations.

4.1.2 Literature search strategy

All peer-reviewed search strategies were developed by the Information Specialist (CS), with input from the project team. Published, peer-reviewed literature was searched using the following bibliographic databases: MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, MEDLINE daily, and EMBASE via Ovid. The CINAHL database was searched via EBSCO. Parallel searches were run in PubMed and The Cochrane Library (Issue 11, 2010).

The search strategy comprised controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Methodological filters were applied to limit the retrieval of articles on 1.5 T MRI systems or 3.0 T MRI systems to health technology assessments (HTAs), systematic reviews, and meta-analyses. No filters were applied to limit the retrieval by study type for articles that compared 1.5 T MRI systems and 3.0 T MRI systems. Appendix 2 shows the detailed search strategies. The search was restricted to articles that were published in English or French between January 1, 2005 and November 29, 2010. Regular alerts were established on MEDLINE, EMBASE, PubMed, and CINAHL, current to April 27, 2011. Grey literature was identified by searching the websites of HTA and related agencies, professional associations, and other specialized databases. Google and other Internet search

engines were used to search for more information. These searches were supplemented by hand-searching the bibliographies and abstracts of key papers, and through contact with appropriate experts and agencies.

4.1.3 Selection criteria for the systematic review

Before the research was started, selection criteria were established for the research question related to the clinical effectiveness of 1.5 T MRI compared with 3.0 T MRI (Table 2).

Table 2: Selection Criteria for Primary Studies on 1.5 T MRI versus 3.0 T MRI

Study details	• Published in English or French • Published from January 1, 2005 onward • RCT of patients exposed to 1.5 T MRI or 3.0 T MRI, or controlled study of patients enrolled in 1.5 T versus 3.0 T programs or cohort study of patients exposed to 1.5 T MRI and 3.0 T MRI • At least 20 patients scanned using 1.5 T MRI and 3.0 T MRI • All sources for safety data
Population	• Patients receiving MRI for clinical conditions
Interventions and comparators	• Each patient received 1.5 T MRI and 3.0 T MRI examinations • Examinations ≤ 1 month apart for chronic conditions, e.g., MS; and ≤ 1 week apart for acute conditions, e.g., stroke
Outcomes	• Impact on diagnosis, clinical management decisions, or patient outcomes • Use of clinically meaningful measures; e.g., categorized lesions, measured degree of stenosis, measured amount of muscle damage • Technical test parameters were considered to be inadequate for drawing relative effectiveness conclusions; e.g., SNR, image quality

MRI = magnetic resonance imaging; MS = multiple sclerosis; RCT = randomized controlled trial; SNR = signal-to-noise ratio; T = Tesla.

4.1.4 Selection method for systematic review

Two reviewers (KB and VF) independently assessed the results of the literature search and selected citations that seemed to satisfy the inclusion criteria. Through consensus, potentially relevant citations were identified and full-text articles were retrieved. All potentially relevant full-text articles presenting harms data were selected. In addition, citations for relevant review articles were selected for background information.

The potentially relevant studies were classified into six clinical areas:
- Neurology
- Cerebrovascular conditions
- Renal artery stenosis
- Coronary artery disease (CAD)
- Musculoskeletal disorders
- Oncology

The six clinical groups were divided between two reviewers and the selection criteria (Table 2) were applied again by both reviewers. Disagreements were resolved by consensus, without the need for a third party.

4.1.5 Data extraction strategy for the systematic review

The included studies were reviewed and data entered into evidence tables created by each author for his or her clinical categories under the following headings: study, patient population, imaging procedure (intervention methods), relevant outcomes (MRI measures), and findings relevant to the clinical situation (Appendix 3). The second clinical reviewer then checked the work of the lead reviewer for each category.

4.1.6 Strategy for validity assessment of studies for the systematic review

Studies were assessed for validity by patient outcome; that is, changes in clinical outcomes, patient management, or diagnosis (Table 3). Studies that reported clinical test parameters were included, whereas studies that reported only technical test parameters were excluded.

Table 3: Strategy for Validity Assessment of Studies

Study Type	Design		Number of Studies
Controlled	Randomized patients to imaging with 1.5 T MRI or 3.0 T MRI, or both		#
	Compared matched groups of patients imaged with 1.5 T MRI or 3.0 T MRI technology; i.e., matched populations at different institutions, one with 1.5 T MRI and one with 3.0 T MRI		#
Observational	Each patient had 1.5 T MRI and 3.0 T MRI (within 1 week for an acute condition and 1 month for a chronic condition)	**Differences in clinical outcomes:** Assessed for patient outcomes after clinical management decisions with different MRI technology	#
		Differences in clinical management: Assessed for clinical management decisions with different MRI technology	#
		Differences in diagnosis: Assessed for diagnostic labelling with different MRI technology	#
		Differences in findings on imaging: Assessed for imaging findings; e.g., lesion number, volume, location	#

MRI = magnetic resonance imaging; T = Tesla.

4.1.7 Information gathering to address research question no. 2

To address the service delivery, personnel, and structural differences between 1.5 T MRI and 3.0 T MRI scanners, information was drawn from several relevant review articles that were identified in the initial literature search , information from web-based sources, and Original Equipment Manufacturer (OEM) materials. In addition, a questionnaire was sent to the five OEMs marketing MRI in Canada. The 11 questions addressed topics such as requests for clinical and economic study information; identification of evidence-based MRI guidelines; key elements of the OEM's top-of-the-line 1.5 T MRI and 3.0 T MRI scanners; differences between the technologies, costs, and options available; clinical benefits, limitations, and safety of 1.5 T MRI

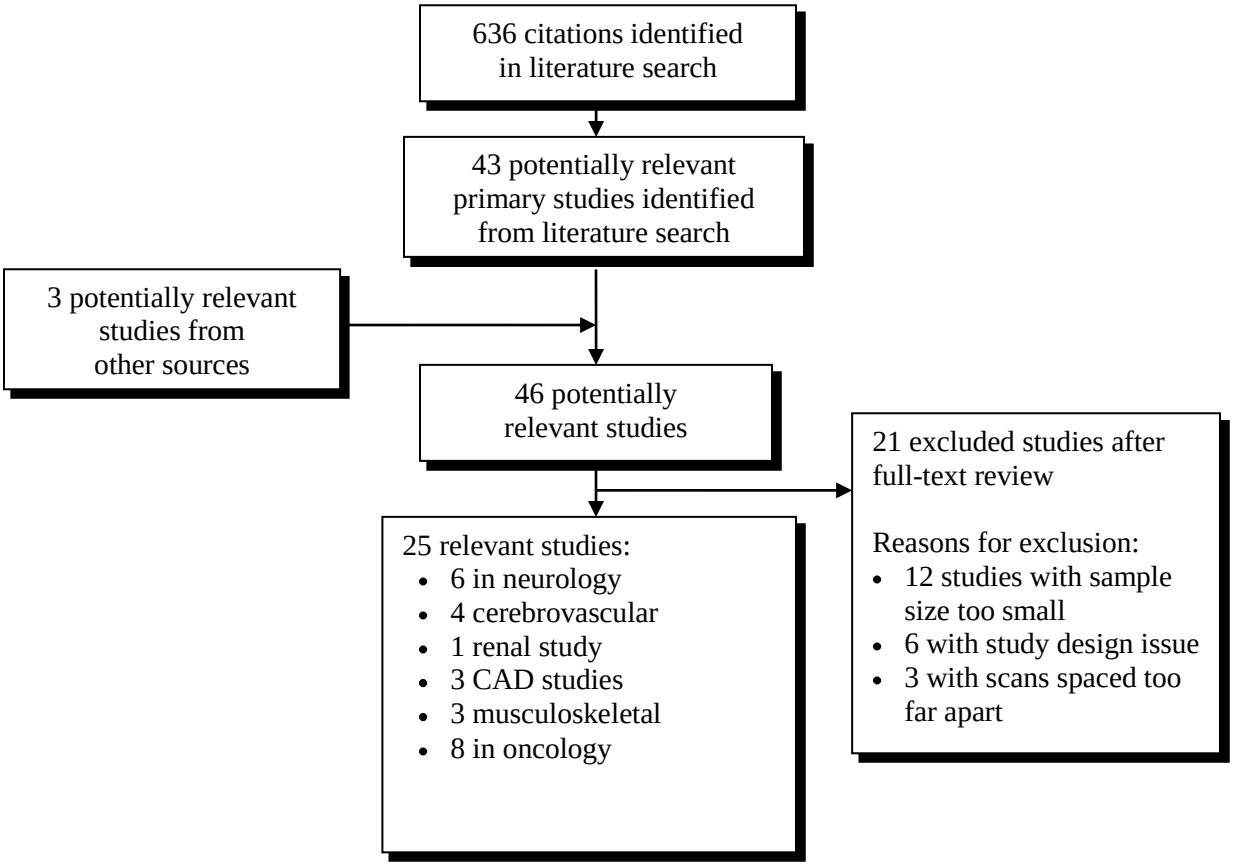
and 3.0 T MRI from the OEM's perspective; typical annual operating costs; and typical scan room renovation costs.

4.2 Results

4.2.1 Quantity of research available for the systematic review

The literature search resulted in 636 citations, from which two clinical reviewers selected 72 potentially relevant publications including 43 primary studies, 27 reviews, and two additional references (case-control studies). Another three primary studies were located via bibliography reviews, for a total of 46 primary studies. The review of the full-text articles and re-application of the inclusion criteria (Table 1) led to the final inclusion of 25 studies. The flow of study selection appears in the PRISMA diagram in Figure 2.[7]

Figure 2: PRISMA Flow Diagram for Study Inclusion



CAD = coronary artery disease; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analysis

4.2.2 Study characteristics for the systematic review

None of the included studies randomized patients to imaging with 1.5 T MRI or 3.0 T MRI and followed them to see whether diagnosis, patient management, or clinical outcomes differed. In addition, none of the studies compared matched groups of patients imaged with 1.5 T MRI to those imaged with 3.0 T MRI and followed them to see whether diagnosis, management, or clinical outcomes differed.

All included studies were prospective and observational, and all examined technical and clinical test parameters. The sample sizes ranged from 20 patients to 65 patients, and all studies involved adults (the ages ranged from 19 years to 86 years). Some studies correlated 1.5 T MRI and 3.0 T MRI findings with pathological findings through biopsy, subsequent surgery, or follow-up testing (Appendix 3).

The studies generally assessed technical test parameters (Appendix 4), but these data on measures such as imaging quality and inter-rater reliability were not extracted into the summary tables or accounted for in the assessment of evidence comparing 1.5 T MRI with 3.0 T MRI.

4.2.3 Data analysis and synthesis for the systematic review

The studies were grouped into six clinical areas:

- Neurology
- Cerebrovascular conditions
- Renal
- CAD
- Musculoskeletal disorders
- Oncology.

a) Neurology

All six neurological studies (one was reported in two publications)[8-14] assessed patients with diagnosed MS or clinically isolated syndrome suggestive of MS. The sample sizes ranged from 22 patients to 41 patients. Scans using 1.5 T MRI and 3.0 T MRI were performed within one month of each other (range of less than 12 hours to a mean of 12 days). The mean or median age of patients ranged from 35 years to 47 years (range 18 years to 64 years), and all studies enrolled more women than men. The mean duration of disease ranged from 34 days (in a study focussed on initial diagnosis)[9,10] to 15 years, with ranges of disease duration extending to 40 years. More details appear in Table 4 and in Appendix 3 Table 12.

Table 4: Neurologic Studies Based on Design and Outcome			
Study Type	**Design**		**Number of Studies***
Controlled	Randomized patients to imaging with 1.5 T MRI or 3.0 T MRI		0
	Compared matched groups of patients with 1.5 T MRI vs. 3.0 T MRI		0
Observational	Each patient had 1.5 T MRI and 3.0 T MRI within a defined time frame	Differences in clinical outcomes	0
		Differences in management	0
		Differences in diagnostic test parameters	1†
		Differences in technical test parameters	5‡

MRI = magnetic resonance imaging; T = Tesla; vs. = versus.
*Studies counted once and categorized according to the highest level of evidence achieved.
†Stankiewicz et al.[13]
‡ Bachmann et al.,[8] Wattjes et al.,[9,10] Di Perri et al.,[11] Nielsen et al.,[12] and Simon et al.[14]

The main findings of the six studies are as follows:

- Four studies (Bachmann et al.,[8] Di Perri et al.,[11] Nielsen et al.,[12] Simon et al.[14]) were intra-individual comparisons of MRI findings for lesion number, volume, and location. In all cases, the authors concluded that 3.0 T MRI was used to identify more (usually smaller) lesions, which tended to be located in more difficult-to-interpret regions of the brain.
- Stankiewicz et al.[13] correlated 3.0 T MRI and 1.5 T MRI findings between an established disability scale and spinal cord function.[13] The authors concluded that MRI findings, in general, were poorly correlated with patient disability and function scores, and that there were no differences between 1.5 T MRI and 3.0 T MRI regarding correlations with these scores.
- Wattjes et al.[9,10] correlated MRI differences with early diagnosis, based on a set of criteria that were established to diagnose MS (the Barkhof MRI criteria). Among the 29 of 40 patients with concordant MRI images, the use of 3.0 T scanning resulted in one additional person being diagnosed with MS, based on the dissemination of lesions in space.

b) Cerebrovascular conditions

Each of the four included studies included patients with a different cerebrovascular condition:

- Stroke[15]
- Intracerebral aneurysms[16]
- Carotid stenosis[17]
- Intracerebral stenosis[18]

The sample sizes ranged from 20 patients to 28 patients. 1.5 T MRI scans and 3.0 T MRI scans were performed within one month of each other (range of less than one hour in the study on acute stroke to a mean of 22 ± 26 days in the study on carotid stenosis). The mean or median age of patients ranged from 58 years to 70 years (range 36 years to 86 years). More details appear in Table 5 and in Appendix 3 Table 13.

Table 5: Cerebrovascular Studies Based on Design and Outcome			
Study Type	**Design**		**Number of Studies***
Controlled	Randomized patients to imaging with 1.5 T MRI or 3.0 T MRI		0
	Compared matched groups of patients with 1.5 T MRI vs. 3.0 T MRI		0
Observational	Each patient had 1.5 T MRI and 3.0 T MRI within a defined time frame	Differences in clinical outcomes	0
		Differences in management	0
		Differences in diagnostic test parameters	1†
		Differences in technical test parameters	3‡

MRI = magnetic resonance imaging; T = Tesla; vs. = versus.
*Studies counted once and categorized according to the highest level of evidence achieved.
† Buhk et al.[18]
‡ Kuhl et al.,[15] Anzalone et al.,[16] Underhill et al.[17]

One study provided clinical correlation. The other three focused on the technical test parameters of 1.5 T MRI and 3.0 T MRI.

- *Study providing clinical correlation*: In Buhk et al.'s 2010 study,[18] the two interpreting radiologists identified three stenoses of the intracerebral arteries using both technologies, although a gold standard test was not applied to validate the MRI findings.
- *Number of ischemic lesions in patients with ischemic stroke*: In Kuhl et al.'s 2005 study[15] of 48 lesions that were identified using both or either 1.5 T MRI and 3.0 T MRI, 3.0 T MRI was used to identify 47 lesions (98%), and 1.5 T MRI was used to identify 36 lesions (75%). One lesion was identified using 1.5 T MRI but not 3.0 T MRI. The authors noted that the additional lesions that were detected using 3.0 T MRI were small and occurred in patients with many small infarcts. Most of these lesions were also detected using 1.5 T MRI scanning.
- *Visualization of residual patency of intracerebral aneurysms treated using Guglielmi detachable coils*: In Anzalone et al.'s 2008 study,[16] the authors concluded that, based on the judgment of the two interpreting radiologists, the results were similar when contrast-enhanced 1.5 T MRI and 3.0 T MRI were used to depict residual aneurysm patency after treatment with Guglielmi detachable coils .
- *Presence or absence, and area of plaque components in asymptomatic patients with carotid stenosis on duplex ultrasonography:* In Underhill et al.'s 2008 study,[17] the results showed that the technologies were equal in identifying plaque components (calcification and lipid-rich necrotic cores). The use of 1.5 T MRI was better at visualizing hemorrhage (15% versus 8%; $P < 0.001$) and calcification measurements were statistically significantly larger ($P = 0.03$) using 3.0 T MRI.

c) Renal artery stenosis

In 2008, Herborn et al.[19] reported on patients with hypertension of unknown origin who were referred for diagnosis or exclusion of renal artery stenosis (RAS). This prospective study enrolled 22 patients (45 renal arteries [three supernumerary arteries]). One patient withdrew consent and was excluded from the analysis. The mean patient age was 67 years (range 45 years to 77 years), and the mean blood pressure was 150/94. Patients underwent 1.5 T MRI and 3.0 T MRI at least 24 hours apart (maximum 29.5 hours; mean 25.25 hours). The dose of contrast that was used with 1.5 T MRI was double that with 3.0 T MRI (0.2 mmol/kg versus 0.1 mmol/kg). Two observers with at least three years' experience interpreting MRI images of

the renal arteries (blinded to the patient) randomly assessed the reduction in luminal diameter for each renal artery lesion.

The results showed that 1.5 T MRI and 3.0 T MRI detected five cases of RAS. The researchers reported that the difference in mean image quality for the two doses and field strengths was not statistically significant. However, they also concluded that with a double-dose of contrast 1.5 T MRI was used to visualize overall vessel length and intraparenchymal branches better than 3.0 T MRI with one dose of contrast. Appendix 3 Table 14 shows the details.

d) Coronary artery disease

Three included studies examined patients with different cardiac-related conditions:

- Suspected CAD[20]
- Acute myocardial infarction (MI)[21]
- Chronic MI[22]

Sample sizes ranged from 20 patients to 65 patients. 1.5 T MRI and 3.0 T MRI scans were performed within one month of each other (range of less than 24 hours to 25 days), and in random order in at least two studies (the order was not reported in one study). The mean age of patients ranged from 60 years to 64 years and approximately 80% were male. More details appear in Table 6 and in Appendix 3 Table 15.

Table 6: CAD Studies Based on Design and Outcome

Study Type	Design		Number of Studies*
Controlled	Randomized patients to imaging with 1.5 T MRI or 3.0 T MRI		0
	Compared matched groups of patients with 1.5 T MRI vs. 3.0 T MRI		0
Observational	Each patient had 1.5 T MRI and 3.0 T MRI within a defined time frame	Differences in clinical outcomes	0
		Differences in management	0
		Differences in diagnostic test parameters	1†
		Differences in technical test parameters	2‡

MRI = magnetic resonance imaging; T = Tesla; vs. = versus.
*Studies counted once and categorized according to the highest level of evidence achieved.
† Cheng et al.[20]
‡ Ligabue et al.,[21] Klumpp et al.[22]

- *Study providing clinical correlation (for detection of CAD)*: In 2007, Cheng et al.[20] reported on the diagnostic accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of 1.5 T MRI and 3.0 T MRI for the detection of CAD in patients awaiting cardiac catheterization for suspected CAD. These patients underwent cardiac catheterization within two weeks of the MRI scans, which were done on the same day. Two blinded observers viewed the images in random order and reached consensus. Regarding the test parameters, the authors reported a trend toward the superiority of 3.0 T MRI over 1.5 T MRI that did not reach statistical significance. The 3.0 T MRI was statistically significantly better at detecting single- and multi-vessel disease ($P < 0.05$). However, there was no statistically significant difference between the two technologies in overall CAD detection.

- *Follow-up after acute MI for assessment of myocardial viability*: In Ligabue et al.'s 2008 study,[21] 35 patients were treated with percutaneous transluminal coronary angioplasty and stent implantation for acute MI. Within four weeks following the percutaneous transluminal coronary angioplasty, patients were scanned using 1.5 T MRI (considered by the authors to be the gold standard) and 3.0 T MRI, a mean of seven days apart. Functional and viability assessments were used to seek the presence and extent of perfusion defects and infarcted tissue. The results showed that the technologies were not statistically significantly different in the eight functional and viability indexes that were used including ejection fraction, stroke volume, cardiac output, end diastolic volume, end systolic volume, summed wall motion score, summed perfusion score, and summed scar score.
- *Follow-up after chronic MI for assessment of myocardial viability*: In Klumpp et al.'s 2009 study,[22] patients with a previous history of MI (mean of 944 days previous, range 93 days to 7,253 days) were assessed for myocardial viability using 1.5 T MRI and 3.0 T MRI in random order four to 25 days apart. The images were interpreted in random order two months later by two blinded, off-site radiologists who were experienced in reading cardiac MRI. The results showed that the two technologies were not statistically significantly different in mean left ventricular function (ejection fraction), extent and localization of MI, and confidence in diagnosis as measured on a qualitative five-point scale.

e) Musculoskeletal disorders

Three studies included patients with the following clinical conditions:

- Temporomandibular joint (TMJ) dysfunction syndrome[23]
- Acute wrist trauma[24]
- Brachial plexus disturbances[25]

The sample sizes ranged from 21 patients to 30 patients. Where reported, 1.5 T MRI scans and 3.0 T MRI scans were performed within a short period of each other. The time gap was not reported in two studies but was assumed to be short. The mean age of patients ranged from 35 years to 52 years, and women made up approximately 60% of patients in the two studies that reported patient demographics. More details appear in Table 7 and in Appendix 3 Table 16.

Table 7: Musculoskeletal Studies Based on Design and Outcome

Study Type	Design		Number of Studies*
Controlled	Randomized patients to imaging with 1.5 T or 3.0 T MRI		0
	Compared matched groups of patients with 1.5 T vs. 3.0 T MRI		0
Observational	Each patient had 1.5 T MRI and 3 T MRI within a defined time frame	Differences in clinical outcomes	0
		Differences in management	0
		Differences in diagnostic test parameters	1†
		Differences in technical test parameters	2‡

MRI = magnetic resonance imaging; T = Tesla; vs. = versus.
*Studies counted once and categorized according to the highest level of evidence achieved.
† Tagliafico et al.[25]
‡ Schmid-Schwap et al.,[23] Stehling et al.[24]

- In 2010, Tagliafico et al.[25] assessed clinical test parameters in imaging the brachial plexus in patients who presented with brachial plexus disturbances (dysesthesia, paresthesia, or motor deficit). The authors noted that pathologic findings were equal with 1.5 T MRI and with 3.0 T MRI (30 of 30 found with both technologies), and clinical diagnoses were the same for 1.5 T MRI and 3.0 T MRI, as both were used to identify nine tumours, metastatic infiltration in 16 patients, and fibre thickening in two patients (nerve tumours and brachial plexus neoplastic involvement were confirmed at histology). However, nerve visibility was statistically significantly better using 3.0 T MRI than 1.5 T MRI on a 1 to 4 scale when assessing the extent of visibility.
- In 2009, Schmid-Schwap et al.[23] and Stehling et al.[24] compared the imaging quality of 1.5 T MRI and 3.0 T MRI, without extension to diagnostic test parameters.
    - Schmid-Schwap et al.[23] enrolled 30 patients with unilateral or bilateral TMJ clicking or clinically suspected anterior disc displacement in at least one joint. Because of factors such as declining to participate, not showing up for a visit, and withdrawing from the study, the study sample included 24 patients. Closed and open-mouth 1.5 T MRI scans and 3.0 T MRI scans were done in random order (the time between scans was not reported but was assumed to be acceptable). Two blinded interpreters — a radiologist and a dentist who specialized in TMJ dysfunction syndrome — independently examined the scans in random order. The results showed that the perceptibility of disc shape and position was reported as superior for 3.0 T MRI compared with 1.5 T MRI for both reviewers ($P < 0.001$).
    - In Stehling et al.'s 2009 study of wrist injury,[24] the visibility of anatomic structures was judged to be superior using 3.0 T MRI. Three independent observers (two radiologists and a hand surgeon) used a five-point qualitative scale to assess the visibility of anatomical structures such as the trabecular structure and fibrocartilage lesions. The scores were 4.6 for 3.0 T MRI and 2.6 for 1.5 T MRI; $P < 0.001$. Three additional lesions were detected using 3.0 T MRI versus 1.5 T MRI (14 lesions versus 11 respectively; no statistical calculation). However, the authors commented that, because of the small amount of pathology and the lack of a gold standard (for example, diagnostic arthroscopy), they were unable to comment on whether the differences in image quality would affect diagnosis, treatment, or the need for further (invasive) investigations such as diagnostic arthroscopy.

f) Oncology

Eight studies examined patients who had cancer or who were being investigated for cancer, covering the following clinical conditions:

- Breast cancer[26]
- Liver cancer[27-29]
- Prostate cancer[30,31]
- Endometrial cancer[32]
- Cervical cancer[33]

The sample sizes ranged from 21 patients to 37 patients. 1.5 T MRI scans and 3.0 T MRI scans were performed within a mean range of 30 minutes to seven days (the time between scans was not reported in two studies, but it was short by implication). The mean age of patients ranged from 50 years to 66 years, with an overall range of 30 years to 81 years. More details appear in Table 8 and in Appendix 3 Table 17.

Table 8: Oncology Studies Based on Design and Outcome			
Study Type	**Design**		**Number of Studies***
Controlled	Randomized patients to imaging with 1.5 T or 3.0 T MRI		0
	Compared matched groups of patients with 1.5 T vs. 3.0 T MRI		0
Observational	Each patient had 1.5 T and 3.0 T MRI within a defined time frame	Differences in clinical outcomes	0
		Differences in management	0
		Differences in diagnostic test parameters	8[†]
		Differences in technical test parameters	0

MRI = magnetic resonance imaging; T = Tesla; vs. = versus
*Studies counted once and categorized according to the highest level of evidence achieved
[†] Beyersdorff et al.,[30] Chang et al.,[27] Kuhl et al.,[26] Torricelli et al.,[31] von Falkenhausen et al.,[28] Hori et al.,[32] Hori et al.,[33] Sofue et al.[29]

Breast cancer

One study[26] compared the MRI images of 37 patients (53 breast lesions; 25 cancer and 28 benign) who were referred for MRI assessment including preoperative staging with biopsy-proven breast cancer (15 patients), clarification of equivocal findings on mammogram or ultrasound (nine patients), familial breast cancer screening (six patients), follow-up after conservation treatment (five patients), and other reasons (not described [two patients]). The mean patient age was 50 years (range 30 years to 69 years). Each woman was imaged first using 1.5 T MRI and then using 3.0 T MRI. The mean time between MRI was 2.4 days (median one day, range one day to nine days). Two radiologists, who were blinded to biopsy and mammography findings but not to MRI strength, independently viewed the MRI images.

The final clinical diagnosis was established by means of an excisional or core biopsy or follow-up of at least 12 months. Forty-nine lesions were detected with 1.5 T MRI and with 3.0 T MRI. 3.0 T MRI was used to detect two additional lesions in one woman with known breast cancer who received preoperative staging. These lesions were missed when 1.5 T MRI was used. This was attributed to patient movement. Differences were found in lesion categorization using the Breast Imaging Reporting and Data System in 10 patients, but clinical correlation was not provided. In this early study published in 2006 (the study years were not reported), the authors concluded that, based on their data, 3.0 T MRI of the breast is "nearing readiness for clinical use".

Primary and secondary liver cancer

Three studies[27-29] enrolled patients with known liver lesions found on MRI, computed tomography (CT), or ultrasound and then scanned them using 1.5 T MRI and 3.0 T MRI. The number of included patients ranged from 22 years to 35 years.

- Chang et al.'s 2006 study[27] and Sofue et al.'s 2010 study[29] provided confirmation of lesion diagnosis and number by comparing MRI findings with a gold standard. In both studies, patients had been diagnosed with liver cancer via pathological examinations. Patients then underwent percutaneous or intraoperative testing or postoperative pathological examinations.
  - In Chang et al.'s study,[27] the images were interpreted by three blinded experienced radiologists. Sensitivities and PPVs versus a gold standard (intraoperative ultrasound, CT, or surgical findings) were calculated for each radiologist. Five of six calculations showed

no statistically significant differences between 1.5 T MRI and 3.0 T MRI. The authors concluded that the diagnostic accuracy of the technologies was equivalent.

- In Sofue et al.'s study,[29] three observers independently reviewed each image and the sensitivity, PPV, and diagnostic accuracy (calculated using the area under the receiver operating characteristics method) of 1.5 T MRI versus 3.0 T MRI were determined. The results showed no statistically significant difference between 1.5 T MRI and 3.0 T MRI in PPV, but the sensitivity for detecting hepatic metastases was higher with 3.0 T MRI than with 1.5 T MRI, as was diagnostic accuracy. The study did not provide details about the clinical impact of the detection of more and smaller liver metastases. Seven false-positive findings on both 1.5 T MRI and 3.0 T MRI were found for all observers.

In 2006, Von Falkenhausen published a study[28] on suspicious liver lesions in 21 patients with 79 focal liver lesions (benign and malignant). Nine of the 21 had pathological confirmation. Of the 79 index lesions, 76 were identified using 1.5 T MRI and 77 were identified using 3.0 T MRI imaging. The authors concluded that 3.0 T MRI of the liver was feasible, and diagnostic findings were comparable to those that were obtained using 1.5 T MRI.

Prostate cancer

Two studies of men with prostate cancer[30,31] used similar designs to compare a 1.5 T MRI endorectal-body phased-array coil with a 3.0 T MRI torso phased-arrayed coil in preoperative prostate cancer staging.

- In Beyersdorff et al.'s 2005 study,[30] 24 men with biopsy-confirmed prostate cancer were referred for preoperative staging before radical prostatectomy (two did not undergo surgery because one had disseminated cancer, and the other had benign disease). All men underwent 3.0 T MRI scanning with a torso coil and 1.5 T MRI scanning with an endorectal coil, with 17 of the 24 men receiving their scans on the same day. Two radiologists independently viewed the images. Blinding was not possible because of visualization of the different coils. Preoperatively, both technologies showed 73% accuracy for local staging. However, a review of images post-surgery showed that the use of 1.5 T MRI displayed statistically significantly better tumour delineation.
- In 2006, Torricelli et al.[31] followed a similar study design, assessing 29 men with biopsy-proven prostate cancer who needed staging before radical prostatectomy. The results showed no statistical differences between 1.5 T MRI and 3.0 T MRI in sensitivity, specificity, PPV, and NPV.

Endometrial cancer

In 2009, Hori et al.[32]studied MRI use in the preoperative staging of 30 women who were diagnosed with endometrial cancer. Each woman was imaged with 1.5 T MRI and 3.0 T MRI in random order and the scans were performed within 30 minutes of each other, followed by total abdominal hysterectomy several weeks later. The mean patient age was 59 years (range 43 years to 75 years). Preoperative MRI staging was compared with findings at surgery (the gold standard) that was performed a mean of 28 days later, to enable the calculation of sensitivity, specificity, PPV, NPV, and diagnostic accuracy for myometrial and cervical invasion, and lymph node metastases. The MRI images were reviewed by two experienced radiologists (blinded to all but patient age and extent of invasion) and scored using a five-point scale. The results showed 1.5 T MRI and 3.0 T MRI to be similar in regional staging and accuracy of predicting the need

for lymphadenectomy; that is, the sensitivity and specificity for the presence of invasion were not statistically different between 1.5 T MRI and 3.0 T MRI for both readers and for all comparison pairs. The authors concluded that the technologies were similar for the pre-surgical evaluation of endometrial cancer.

Cervical cancer

Over a similar time frame in 2009, Hori et al.[33] prospectively evaluated the efficacy of 3.0 T MRI compared with 1.5 T MRI in the preoperative staging of cervical cancer. MRI findings were compared with surgicopathologic findings as the gold standard. The 31 women (mean age 51 years, range 27 years to 71 years) had biopsy-proven, untreated cervical cancer and received 1.5 T MRI and 3.0 T MRI examinations in random order 30 minutes apart, followed by hysterectomy a mean of 34 days later (range 13 days to 75 days). The MRI images were reviewed by two blinded experienced radiologists, and the extent of invasion (parametrial and vaginal) and lymph node metastases was scored using a five-point scale. MRI findings versus the gold standard detected no statistically significant differences between 1.5 T MRI and 3.0 T MRI technologies in diagnostic accuracy, sensitivity, specificity, PPV, or NPV. The authors concluded that 3.0 T MRI was not superior to 1.5 T MRI for the presurgical evaluation of patients with cervical carcinoma.

4.2.4 Harms

More than 1,800 objects have been tested using 1.5 T MRI scanners, and approximately 600 objects have been tested using 3.0 T MRI scanners.[5] Patients with implants and devices that have elongated configurations or that form conducting loops should not undergo 3.0 T MRI scanning until ex vivo heating has been assessed to determine the relative risks.[5,34-36] For example, a new generation of pacemakers was released in 2011 which is currently only 1.5 T compatible.[37] A resource for determining the status of devices and MRI can be found at www.MRIsafety.com.[36] This web site provides a list of implants, devices, materials, and other products, divided into categories to facilitate access and review of pertinent information.

Three additional points relevant to harms:

- The 5 Gauss (0.0005 T) magnetic field that is associated with 1.5 T MRI and 3.0 T MRI systems is usually confined to the scanning room walls by using active magnetic shielding. However, the attraction of ferromagnetic objects that are inadvertently placed near a scanner will exhibit an abrupt pull from a 3.0 T magnet compared to a gradual pull with a 1.5 T magnet.[34]
- Pulsed radiofrequency fields can induce currents resulting in heating of the body and, depending on the situation, cause patient burns.[36]
- The noise level of 3.0 T MRI scanning approaches twice that of 1.5 T MRI scanning and, depending on the pulse sequence used can be in excess of 130 decibels. Although manufacturers have incorporated sound-dampening material, patients using 3.0 T MRI scanning must use hearing protection.[34,36]

Note: This section is taken from a review of harms information in the literature and not from the individual studies that were assessed, where harms were not reported.

4.2.5 Response to survey of MRI original equipment manufacturers

A customized survey was sent to the five MRI OEMs in Canada. Two of the five companies responded, neither in the requested format. Substantial information was provided by one respondent and anecdotal comments by the other respondent. The material that was supplied by the first OEM was useful in several sections of this report.

5 MRI USE

5.1 MRI Installations in Canada

The 2009 Medical Imaging Technology survey published by the Canadian Institute for Health Information (CIHI) collected data from all known public or private health care facilities in Canada where MRI scanners were installed and operational as of January 1, 2009.[1] These data are shown in Table 9.

Table 9: Installed MRI Devices in Canada (January 1, 2009)[1]

Province	MRI Devices Installed	3.0 T	Facility
BC	23	-	
AB	24	2	Foothills (Calgary); Cross Cancer (Edmonton)
SK	5	-	
MB	8	-	
ON	81	5	Hamilton: St. Joseph's Health Centre Toronto: Hospital for Sick Children, Sunnybrook, Toronto Western, University Health Network
QC	53	1	Hôpital Général du Lakeshore (Pointe-Claire)
NB	6	-	
NL	3	-	
NS	8	-	
PE	1	-	
TOTAL	**212**	**8**	

AB = Alberta; BC = British Columbia; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NS = Nova Scotia; ON = Ontario; PE = Prince Edward Island; QC = Quebec; SK = Saskatchewan.

NOTE: There are no MRI devices installed in the three territories (Yukon, Northwest Territories, Nunavut).

5.2 Mean Examinations per MRI Scanner in Canada

CIHI reported a national mean number of 5,750 examinations per MRI scanners in 2009.[1] Three provinces were above the mean: Manitoba, Ontario, and Alberta. The three provinces with the lowest mean numbers of examinations per MRI scanner were Prince Edward Island, British Columbia, and Nova Scotia.[1]

5.3 MRI Use (Examinations per 1,000 People)

5.3.1 MRI use in Canada (number of examinations per 1,000 population)

CIHI reported a national average of 41.4 MRI examinations per 1,000 people in 2008-2009.[1] The highest utilization rates were in Alberta and New Brunswick, where the utilization rate was double that of the provinces with the lowest utilization rates: Prince Edward Island, and Newfoundland and Labrador. The CIHI data show (approximate) rates of scans per 1,000 people: Alberta, with 54 per 1,000, and New Brunswick, with 51 per 1,000; Prince Edward Island, with 23.0 per 1,000, and Newfoundland and Labrador, with 24.2 per 1,000.[1]

5.3.2 MRI use in Organisation for Economic Co-operation and Development countries

Data collected in CIHI Medical Imaging Technology surveys are periodically reported to the Organisation for Economic Co-operation and Development. This allows a review of Canada's utilization compared to other Organisation for Economic Co-operation and Development member countries. Canada's 2008 mean utilization rate of 41.4 per 1,000 people was lower than the Organisation for Economic Co-operation and Development mean of 48.5 per 1,000 people. The utilization ranged from 12.7 examinations per 1,000 people in Korea to 98.1 examinations per 1,000 people in Greece.[1]

6 DISCUSSION

The impacts of MRI innovation on patient management and clinical outcomes are difficult to assess. Studies require a broad range of patients with several clinical conditions, and long and complete patient follow-up. The outcomes need to be clinically relevant and, ideally, the impact on diagnosis, patient management, or patient outcomes needs to be assessed. Studies with hundreds of patients per study arm can be required to measure the small incremental differences between similar technologies such as different magnet strengths in MRI. MRI has applications in many clinical areas, and each can have unique considerations.

Advice about the selection of MRI type was sought from Dr. Ian Smith, the Director General, Institute for Biodiagnostics, National Research Council Canada. "The first question I ask people looking for advice is, 'What will you do with the MRI?' If it is routine scanning of brains and joints, a 1.5 is fine. If it is sophisticated measurements such as functional MRI or diffusion tensor measurements, the 3 T is essential." (Dr. Ian Smith, National Research Council Canada, Winnipeg, personal communication, 2011 Jan)

6.1 Summary of Results

No identified studies examined whether the use of 3.0 T MRI scanners would result in a change in patient or health outcomes, or a change in clinical management, compared with 1.5 T MRI scanners.

All of the 25 included studies reported on clinical test parameters. The six clinical areas were neurology (mainly MS), cerebrovascular conditions, renal artery stenosis, CAD, musculoskeletal disorders, and oncology (breast cancer, liver cancer, prostate cancer, endometrial cancer, and cervical cancer). The authors most commonly reported that 3.0 T MRI was equivalent to 1.5 T MRI for various diagnostic and technical outcomes. In a few cases, 1.5 T MRI scanners were found to be better than 3.0 T MRI scanners; for example, tumour delineation of the prostate. And, in some other instances, 3.0 T MRI scanners outperformed 1.5 T MRI scanners. For example, advantage for 3.0 T MRI was seen in:

- lesion detection in MS
- identification of single or multi-vessel disease in patients with CAD
- identification of disc shape and position for TMJ
- nerve visibility for brachial plexus
- visibility of anatomic structures in the wrist
- identification of fibrocartilage lesions
- diagnostic accuracy for hepatic metastases
- sensitivity for detecting hepatic metastases.

All the identified studies were observational and thus did not stringently control for potential biases that may result in a higher chance of differences being falsely detected or actual differences not being detected. Appropriate to these study goals, a small number of patients (maximum 65) prospectively received repeat testing with 1.5 T MRI and 3.0 T MRI within a short time frame. Two or more interpreters (usually radiologists), generally blinded to patient details and magnet size, assessed the images using standardized quantitative measurements and qualitative questionnaires. In some cases, the findings were recorded independently and then compared. In other cases, the findings were agreed to by consensus.

Safety information collected from reviews, not individual studies, indicated the greater magnetic effect of 3.0 T MRI scanners may make them unsuitable for patients with specific implanted devices; to date, more than 1,000 devices and other objects that have not yet been deemed to be safe with the use of the 3.0 T MRI. Increased heat and increased noise with 3.0 T MRI may also be of concern.

One relevant study by Ohba et al.[38] was identified through the alert process. The study was a non-randomized, prospective comparative study and the results did not affect the conclusions of the systematic review. Ohba et al. provided evidence that 3.0 T MRI and 1.5 T MRI were similar in identifying 58 malignant pulmonary nodules in 76 patients when using diffusion-weighted imaging. The authors also noted that further software developments for 3.0 T MRI would reduce lung artifacts, thus improving the correlation with apparent diffusion coefficient values and the F-fluorodeoxyglucose uptake on the positron-emission tomography.

6.2 Limitations of Assessment

6.2.1 Clinical benefits, limitations, and safety

The main limitation for the systematic review was the lack of evidence linking the clinical test findings from using different MRI technologies to an impact on clinically meaningful outcomes; that is, diagnosis, patient management, and clinical outcomes. Although some studies reported that 3.0 T MRI was superior in technical outcomes such as image detail, it was unclear that this would make a difference to patients and what the magnitude of the difference would be. Studies also tended to be small, generally with 20 patients to 30 patients enrolled. Several articles acknowledged this limitation and suggested that studies would need to be larger, enrol a broader spectrum of patients, and include more extensive patient follow-up to draw clinically valid conclusions.

The included literature for the systematic review was limited to those studies meeting selection criteria. Therefore, a number of indications for MRI were excluded; for example, brain tumours, epilepsy, breast imaging, and knee and shoulder pathology. Similarly, all included studies involved adult populations and pediatric populations were not studied.

Although the funding source was sought for each included study, 22 of the 25 (88%) included studies did not report funding or conflicts of interest. Of the remaining three studies, one, each, was funded by the German Research Foundation, Dutch Foundation for MS Research, and Pfizer. Regarding industry affiliation, studies reported one author employed by GE, two by Philips, and one by Pfizer.

An issue in the interpretation of the results of these studies is the increasing sophistication and changing performance of MRI devices. Although only recent studies were included (published in 2005 or later), some studies were performed as early as 2003 when 3.0 T MRI was in the early stages of introduction. Current 1.5 T MRI and 3.0 T MRI machines would perform differently from those that were used in the studies, suggesting that the findings from the earlier studies would not be reproducible today.

The MRI literature is limited in part due to federal regulations that only require device manufacturers to provide proof of safety and technical performance consistency according to specifications (scientific evidence of clinical utility or patient benefit before licensing is unnecessary). This does not provide an impetus for manufacturers to conduct studies that explore the impact of device technology on clinical outcomes.

6.2.2 Service delivery, personnel, and structural differences

Short time lines for report completion, time of year (December and January), and extensiveness of the survey requests limited the information received from OEMs. The information that is needed to adequately assess service delivery, personnel, and structural differences is often unpublished, inaccessible, and anecdotal. Similarly, data on utilization were limited to information that was collected in January 2009 (2010 data have been collected but are not yet released by CIHI). More than the other sections of this report, the information on service delivery and personnel are not immediately transferable to other jurisdictions.

7 CONCLUSIONS

The evidence on clinical test parameters shows that 3.0 T MRI, in general, performs as well as or better than 1.5 T MRI for the studies included in this review. Study design is, however, limited by factors such as design and sample size. The evidence does not indicate whether patients will receive different clinical management or experience different health outcomes. That is, the relative clinical effectiveness of 3.0 T MRI compared with 1.5 T MRI cannot be determined. There is a lack of evidence on the safety of using 3.0 T MRI with implanted devices. Other factors to consider are the extent to which a facility with a 1.5 T MRI requires renovation to house a 3.0 T MRI, the MRI experience of staff, the need for research applications, and the need for current and future clinical applications.

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APPENDIX 1: PROS AND CONS OF 1.5 T MRI VERSUS 3.0 T MRI

Table 10: Budgetary Cost Comparison, 1.5 T MRI to 3.0 T MRI (for example, only)*

	1.5 T MRI	1.5 T MRI	1.5 T MRI	Magnitude of Difference (1.5 T MRI to 1.5 T MRI)		3.0 T MRI	3.0 T MRI	3.0 T MRI	Magnitude of Difference (3.0 T MRI to 3.0 T MRI)		Magnitude of Difference (1.5 T MRI to 3.0 T MRI)	Magnitude of Difference (1.5 T MRI to 3.0 T MRI)
Capital (MRI only)	**Basic**	**Mid**	**Premium**	**Basic vs. Prem.**		**Basic**	**Mid**	**Premium**	**Basic vs. Prem.**		**Basic vs. Basic**	**Premium vs. Premium**
MRI system cost	**32 Channel**	**48 Channel**	**64 Channel**			**48 Channel**		**64 Channel**				
(Active shielding)	$1,788,200	$1,788,200	$1,788,200			$2,642,200		$2,642,200				
Alternative gradients and receiver channels		$99,455	$198,910					$99,455				
*Clinical Options**			$658,300					$658,300				
Angio DOT**		$33,155	$33,155					$33,155				
Tim Table/Angio DOT **		$62,160	$62,160					$62,160				
Cardiac DOT**		$62,160	$62,160					$62,160				
Knee DOT**		$16,575	$16,575					$16,575				
Total	**$1,788,200**	**$2,061,705**	**$2,819,460**	**$1,031,260**		**$2,642,200**		**$3,574,005**	**$931,805**		**$854,000**	**$754,545**
Other hardware & software available	Yes	Yes	Yes	Yes		Yes		Yes				
Reference	Siemens Canada Limited, unpublished data, 2010											

MRI = magnetic resonance imaging; T = Tesla; vs. = versus.

* Clinical options example (will vary depending on programs supported by the imaging service and site preference)
** DOT (Day Optimization Throughput): Technologist scanning assistance program

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Safety Issue	**3.0 T MRI Pro**	**3.0 T MRI Con**
Immediate fringe field surrounding magnet	--	A ferromagnetic object inadvertently brought into the scan room will experience a sharp increase in attraction toward the 3.0 T MRI magnet upon approach to the scanner (versus a 1.5 T MRI).[34]
Implanted devices	--	Not all objects tested on a 1.5 T MRI have been tested on a 3.0 T MRI; therefore, if a 3.0 T is the only scanner on site, patients with certain implanted devices cannot be scanned.[34]
Consequence of failed actively shielded magnet	--	If active magnetic shielding malfunctions, the unshielded primary magnet field will bloom to several times its normal size and the extended fringe field may interfere with nearby CT, PET, and other imaging equipment not affected by a 1.5 T MRI. Patient monitoring equipment, drug delivery systems, and life support systems may be affected.[34]
Gradient noise	--	Higher gradient performance at 3.0 T MRI results in higher sound pressure levels (although manufacturers have improved techniques to dampen the noise).[34]
Pulsed radiofrequency (RF) fields/ Specific Absorption Rate (SAR)	--	Heating potential is notably higher and more significant at 3.0 T. Higher RF power levels result in limitations on SAR that may not allow the shortest possible scan times using 180 degree RF pulses. Many manufacturers have incorporated reduced tip angle pulse techniques to mitigate this problem.[39]
Imaging coils and cable leads	--	If the coil array, cable assembly, or connector malfunctions and is in physical contact with the patient, skin irritation or burning may occur. The use of a higher magnetic field and higher radiofrequency power levels make such a failure at 3.0 T more critical.[34,39]
Technical Issues	**3.0 T MRI Pro**	**3.0 T MRI Con**
Signal to Noise Ratio (SNR)	SNR received at 3.0 T MRI is approximately twice that of SNR received on a 1.5 T system, hence the abundance of SNR can be used to improve image quality or decrease scan time.[40,41]	--
Parallel Imaging (PI)	PI techniques reduce scan time but are accompanied by loss of signal; however, the resulting image quality can be comparable to a 1.5 T due to the abundance of signal at 3.0 T.[40-42]	--
Relaxation rates	Increased T1 relaxation time for solid tissue and the relatively constant T1 for blood results in an overall improvement in blood vs. background tissue contrast when MR angiography pulse sequences are used.[41,42]	Conventional spin echo pulse sequences cannot be used to produce ideal T1 contrast weighted scans since T1 relaxation time increases with the magnetic field strength. Alternative pulse sequences such as T1 weighted gradient echo, spoiled gradient echo, or magnetization-prepared rapid gradient echo can be used instead.[40]

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Technical Issue	**3.0 T MRI Pro**	**3.0 T MRI Con**
Spatial resolution	Increased SNR leads to an ability to increase in-plane resolution or decrease slice thickness; i.e., higher spatial resolution results in improved image clarity and diagnostic strength.[40]	--
Temporal resolution	Improved temporal resolution occurs with shorter scan times.[40]	--
Artifacts from breathing and motion	Decreased scan times help reduce data artifacts related to breathing and patient motion in those with difficulty holding still during the scanning process.[43]	Artifacts resulting from breathing or any type of motion including flowing blood or pulsation of cerebrospinal fluid are more prominent on 3.0 T MRI vs. 1.5 T MRI. To various extents, manufacturers offer motion-compensating features to reduce or mitigate the problem.[44]
Spectroscopic imaging	Improved spectral resolution or the ability to visualize changes in peaks in metabolites. Fat-water suppression techniques are also improved; especially beneficial for musculoskeletal studies in which fat suppression imaging are important.[41,45]	--
Functional MRI using the BOLD technique	At 3.0 T MRI, clinical BOLD functional imaging studies are excellent, practical, and robust. Greater susceptibility contrast sensitivity and higher SNR inherent to 3.0 T scanning can produce up to a 40% increase in detected activation.[41,42]	--
Diffusion Weighted Imaging (DWI)	Increased sensitivity for detection of ischemic lesions in acute stroke.[41,45]	Increased susceptibility may lead to image distortion during echo planar MRI, which is typically used for DWI. Planar imaging techniques may significantly reduce DWI susceptibility artifacts.[41]
Diffusion Tensor Imaging (DTI)	Images of white matter tracts are improved at 3.0 T MRI compared with 1.5 T MRI; 3.0 T enables DTI at higher spatial resolution or shorter acquisition times.[42]	Geometric warping artifacts common to EPI pulse sequences may limit anatomic fidelity, especially in area of high magnetic field susceptibility resulting from high interfaces such as brain-to-air-to-bone in the area of the skull base and the posterior fossa.[42]
Perfusion-Weighted Imaging	The accuracy of cerebral perfusion is improved at 3.0 T MRI because of the increased number of sampling points during the first pass of gadolinium contrast agent compared with DWI imaging at 1.5 T MRI with much lower temporal resolution and a smaller number of sampling points.[41,45]	--
Magnetic resonance angiography (MRA)	Improved Contrast to Noise Ratio (CNR). The longer T1 of background tissues can be exploited for superior inflow MRA. Vessels show more hyper-intense signals with better background tissue suppression. Small vessel visualization is improved.[42]	--

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Technical Issue	**3.0 T MRI Pro**	**3.0 T MRI Con**
Arterial Spin Labelling (ASL)	Signal captured from blood is used to image vessels with the ASL pulse sequence. ASL at 3.0 T MRI have higher SNR and longer T1 relaxation, resulting in more reliable ASL.[41]	--
Magnetic susceptibility	Increased magnetic susceptibility can have a positive effect due to 3.0 T being more sensitive to the deposition of blood products (that is, hemosiderin). Improved imaging for brain hemorrhage can be seen in head trauma or stroke. 3.0 T can be useful for dynamic susceptibility weighted perfusion MRI to determine functional parameters such as cerebral blood flow.[41,46]	There can be a signal void in areas of air-to-tissue interfaces such as the frontal sinus, skull base, orbits, and frontal lobes of the brain. Hyper- and hypo-intense signal artifacts due to the presence of implanted metal hardware may be reduced by use of wider receiver bandwidth and longer echo train lengths. Susceptibility leads to dephasing, geometric distortion and signal loss, typically in gradient echo pulse sequences.[41,46]
Chemical shift	MR spectroscopy benefits from an increased chemical shift and improved spectral resolution.[41,46]	Chemical shift artifacts are a disadvantage for imaging cartilage and bone interfaces of musculoskeletal areas.[46]
Dielectric artifacts	--	Radiofrequency waves transmitted from the transmitter coil into the patient are reduced in speed and wavelength in various tissues. As a result, there can be strong variations in signal intensities across the images, brightening in regions away from the receiver coil, or dark areas caused by constructive or destructive interference from standing waves. The dielectric artifacts are more prominent on 3.0 T MRI vs. 1.5 T MRI systems and presents as a challenge when imaging the heart. New 3.0 T scanners use multi-transmit radiofrequency or appropriate modulation in amplitude and phase of the radiofrequency pulse to reduce the problem. Phased array coils and PI may also help.[40,42,46]
Gadolinium	A standard dose of gadolinium administered for examinations done on a 1.5 T MRI may result in greater sensitivity in 3.0 T MRI (that is, less contrast may be used or the same dose may improve CNR).[41,42]	-
Imaging coils	--	The variety of coils for 3.0 T MRI scanners may be limited, depending on the generation of the scanner, especially for systems where the ADC converter is integrated into the imaging coil.[40,43]

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Clinical Condition	**3.0 T MRI Pro**	**3.0 T MRI Con**
Brain: Multiple sclerosis	Lesion visualization is improved.[41,47]	--
Brain: DWI for stroke	Increased sensitivity for detection of ischemic lesions, especially in patients with multiple cerebral embolisms.[41,47,48]	Image distortion in echo-planar DWI due to susceptibility; can be reduced by use of PI.[41,47,48]
Brain: DTI	Imaging of white matter tracts is improved at 3.0 T MRI versus 1.5 T MRI.[42,45]	Geometric warping artifacts common to EPI pulse sequences may limit anatomic fidelity, especially in areas of high magnetic field susceptibility resulting from high interfaces such as brain-to-air-to-bone at the skull base and the posterior fossa.[42]
Brain: Spectroscopy (MRS)	Improved spectral resolution for evaluation of metabolites that could be obscured at 1.5 T MRI. Ability to perform multinuclear spectroscopy to analyze many neurological disorders. The gain in SNR and improved line separation at 3.0 T enable use of smaller voxels, which results in an improved quantification of metabolites, especially for the adjacent creatine and choline peaks.[41,45,49]	--
Brain: Dynamic Susceptibility-Weighted Perfusion MRI (DSW-PMR)	Improved because of the increase in magnetic susceptibility effects. Improved diagnostic information to help determine brain tissue viability after stroke or TIA. The accuracy of cerebral perfusion is improved at 3.0 T MRI owing to the increased number of sampling points during first pass of gadolinium contrast agent compared with DSW-PMR imaging at 1.5 T MRI with lower temporal resolution (e.g., 1.5 seconds per dynamic acquisition) and a smaller number of sampling points.[41,45]	--
Brain: Functional MRI	Increased CNR using BOLD technique. Improved sensitivity and specificity.[41,48]	--
Spine	Improved image quality with 3.0 T MRI DTI vs. 1.5 T MRI.[48]	Decreased fluid contrast associated with prolonged T1. Can be resolved by use of T1 fluid-attenuated inversion recovery (FLAIR), which delineates soft tissue, CSF, disc, and bone interfaces well.[42]
Liver	Effects of fat saturation are improved at 3.0 T MRI because of stronger chemical shift between fat and water.[43]	3.0 T MRI is more sensitive to respiratory motion, vascular pulsation, and dielectric effect. Tissue heating is also a concern. Dual phase imaging can be problematic because the phase echoes are too close together. Adrenal gland imaging may be challenging. Chemical shift artifacts are more pronounced at fat-to-water interfaces.[48]

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Clinical Condition	**3.0 T MRI Pro**	**3.0 T MRI Con**
Pelvis	Structures of the prostate gland may be demonstrated adequately without insertion of an endorectal coil.[48]	Optimal high resolution imaging of the prostate best done with an endorectal coil and pelvic coil combination.
Breast	Improved spatial and temporal resolution capabilities; improved detection and characterization of breast cancer with 3.0 T MRI.	--
Musculoskeletal system	Higher SNR, smaller field of view, thinner slices, and increased spatial resolution can be obtained. Enhanced detection of articular cartilage tears of the shoulder and hip labrum, triangular fibrocartilage complex tears of the wrist, and diagnosis and staging of various derangements of the knee and elbow.[42,48]	T1 increased by 10% to 30% when imaging at 3.0 T MRI vs. 1.5 T MRI. Repetition time must be increased to maintain T1 weighted contrast. The increase in TR is typically about 20%, which translates into a longer TR time. Spectral fat suppression is sensitive to magnetic field inhomogeneity, which limits its use in tissues displaying susceptibility artifacts and in the postoperative areas with hardware due to enhanced artifacts from metal.[42,50]
Cardiac	Ability to obtain higher spatial and temporal resolution. (Increased SNR and decreased imaging time compared with a 1.5 T MRI.) Perfusion images provide better visual delineation of perfusion abnormalities and cardiac ischemia evaluation.[48,51,52]	Cine sequences using steady state free precession pulse sequences for cardiac imaging to display wall motion and LVEF at 3.0 T MRI can be problematic due to increased artifacts from radiofrequency inhomogeneity (dark banding or flow artifacts). MR systems equipped with multi-transmit radiofrequency PI or techniques to modulate the amplitude and phase of radiofrequency pulses can reduce the dark banding artifacts.[48,50-52]
Pediatric imaging	Improved image quality due to higher SNR is available to demonstrate the small anatomical structures of a pediatric patient, and shorter scan times result in reduced total visit time.	--
Vascular	3.0 T MRI TOF imaging due to the longer T1 of background tissue; results in background tissue suppression and higher visibility of contrast in the vascular structures. Use of PI for non-contrast and contrast-enhanced techniques allow for shorter scan times, with increased resolution. Improved temporal resolution vs. 1.5 T MRI.[41,48]	--

ASL = arterial spin labelling; BOLD = blood oxygen level-dependent; CNR = contrast-to-noise ratio; CSF = cerebrospinal fluid; CT = computed tomography; DTI = diffusion tensor imaging; DWI = diffusion-weighted imaging; EPI = echo planar imaging; FLAIR = fluid attenuation inversion recovery; LVEF = left ventricular ejection fraction; MRA = MR angiography; MRI = magnetic resonance imaging; MRS = MR spectroscopy; PET = positron emission tomography; PI = parallel image; PMR = perfusion MR; SAR = Specific Absorption Rate; SNR = signal-to-noise ratio; T = Tesla; TIA = transient ischemic attack; TOF = time-of-flight; vs. = versus.

APPENDIX 2: LITERATURE SEARCH STRATEGY

OVERVIEW	
Interfaces:	Ovid
Databases:	Ovid EMBASE <1996 to 2010 Week 46> Ovid Medline In-Process & Other Non-Indexed Citations, Ovid Medline Daily and Ovid Medline 1950 to Present (date search was run) **Note:** Subject headings have been customized for each database. Duplicates between databases were removed in Ovid.
Date of Search:	November 29, 2010
Alerts:	Monthly search updates began November 29, 2010 and ran until April 27, 2011
Study Types:	All study types were retrieved for research Question 1. Methodological filters were applied to limit the retrieval to health technology assessments, systematic reviews and meta-analyses for Question 2.
Limits:	Publication years 2005-November 29, 2010 Languages: English, French

SYNTAX GUIDE	
/	At the end of a phrase, searches the phrase as a subject heading
.sh	At the end of a phrase, searches the phrase as a subject heading
MeSH	Medical Subject Heading
fs	Floating subheading
exp	Explode a subject heading
*	After a word, a truncation symbol (wildcard) to retrieve plurals or varying endings
adj	Requires words are adjacent to each other (in any order)
Adj#	Adjacency within # number of words (in any order)
.ti	Title
.ab	Abstract
.hw.	Heading Word; usually includes subject headings and controlled vocabulary
.mp.	Mapped Word
.jw.	Journal Word
.md. .pt.	Methodology field Publication type
.rn.	CAS registry number
use pmez	Select Medline results
use emef	Select Embase results

Multi-database Strategy	
Line #	**Search Strategy**
1	Magnetic Resonance Imaging/ or Nuclear Magnetic Resonance Imaging/ or (magnetic resonance imag* or MR imag* or MRI* or fMRI* or MR tomography or magnetization transfer contrast imag* or magnetisation transfer imag* or magnetization transfer imag* or magnetisation transfer imag* or chemical shift imag* or NMR imag* or zeugmatography or NMR tomography or proton spin tomography).ti,ab.
2	("3.0 tesla" or "3. 0 tesla").ti,ab.
3	(3 tesla or three tesla or "3.0 T" or "3.0-T" or "3.0T" or "3. 0T » or « 3. 0-T » or « 3. 0 T » or « 3 T » or « 3-T » or « 3T »).ti,ab.
4	2 or 3
5	("1.5 tesla" or "1. 5 tesla").ti,ab.
6	(« 1.5-T » or « 1. 5-T » or « 1. 5 T » or « 1.5T » or « 1. 5T" or "1.5 T").ti,ab.
7	5 or 6
8	1 and 4 and 7
9	limit 8 to yr="2005 -2011"
10	9 use emef
11	10 not conference abstract.pt.
12	9 use pmez
13	11 or 12
14	limit 13 to (english or french)
15	meta-analysis.pt.
16	meta-analysis/ or systematic review/ or meta-analysis as topic/ or exp technology assessment, biomedical/
17	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab.
18	((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab.
19	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab.
20	(data synthes* or data extraction* or data abstraction*).ti,ab.
21	(handsearch* or hand search*).ti,ab.
22	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab.
23	(met analy* or metanaly* or health technology assessment* or HTA or HTAs).ti,ab.
24	(meta regression* or metaregression* or mega regression*).ti,ab.
25	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.
26	(medline or Cochrane or pubmed or medlars).ti,ab,hw.
27	(32rench3232 or health technology assessment or evidence report).jw.
28	(meta-analysis or systematic review).md.
29	or/15-28
30	1 and 4 and 29
31	1 and 7 and 29
32	30 or 31

Multi-database Strategy	
Line #	**Search Strategy**
33	32 use emef
34	33 not conference abstract.pt.
35	32 use pmez
36	34 or 35
37	limit 36 to yr=”2005 – 2011”
38	limit 37 to (english or french)
39	(“3.0 tesla” or “3 0 tesla” or “3 tesla” or three tesla).ti,ab.
40	(“1.5 tesla” or “1. 5 tesla” or “1 5 tesla”).ti,ab.
41	39 and 40
42	41 not conference abstract.pt.
43	42
44	limit 43 to yr=”2005 – 2011”
45	limit 44 to (english or french)
46	14 or 38 or 45

Other Databases		
PubMed	Same MeSH, keywords, limits, and study types used as per MEDLINE search, with appropriate syntax used.	
The Cochrane Library Issue 11, 2010	Same MeSH, keywords, and date limits used as per MEDLINE search, excluding study types. Syntax adjusted for The Cochrane Library databases.	
CINAHL (EBSCO interface)	Same keywords, and date limits used as per MEDLINE search, excluding study types. Syntax adjusted for EBSCO platform.	

Grey Literature

Dates for Search:	November 18, 2010 to December 3, 2010
Keywords:	MRI, magnetic resonance imaging, Tesla, 3.0 T, 3.0 T, 1.5 T
Limits:	Publication years 2005 to 2010

The following sections of the CADTH grey literature checklist, *Grey matters: a practical tool for evidence-based searching* (http://www.cadth.ca/index.php/en/cadth/products/grey-matters), were searched:

- Health Technology Assessment Agencies
- Clinical Practice Guidelines
- Advisories and Warnings — device
- Internet Search
- Open Access Journals

APPENDIX 3: EVIDENCE TABLES

Table 12: Neurological Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to Clinical Situation**
MRI FOR DIAGNOSTIC LABELLING				
Wattjes et al., 2006[9,10] Germany 2004-2005 Study funding: NR	• n = 40 (+ 20 healthy volunteers) • Inclusion criteria: CIS suggestive of MS (single demyelinating episode); age at symptom onset 18 to 59 years; CIS onset until MRI < 3 months • Patients: M/F, 10/30; median age 35 (range 18 to 55); median disease duration at MRI 34 days (range 12 to 67)	• IV corticosteroid therapy x 3 days given 2 to 4 weeks before MRI. • 1.5 T MRI and 3.0 T MRI performed in randomized order separated by 24 to 36 hours. • MRI were Philips Medical Systems • 2 radiologist interpreters were blinded to clinical findings and MRI strength; viewed images together in random order to reach consensus • MRI and clinical f/u to assess conversion to definite MS at 3 to 4 and 6 to 7 months	• High signal white matter lesions > 3mm: ○ Total number ○ Location • Barkhof imaging criteria • DIS	• 11 patients (28%) fulfilled 1 additional Barkhof MRI criterion at 3.0 T MRI • 3.0 T MRI influenced CIS classification for image criteria, but not for diagnostic criteria
Nielsen et al., 2006[12] Denmark Study years: NR Study funding: NR	• n = 28 • Inclusion criteria: Acute optic neuritis as CIS or part of RRMS • Patients: M/F, 6/22; median age 36 (range 18 to 52); median duration of optic neuritis at MRI, 25 days (range 5 to 70 days); median disease duration for those with RRMS, 4.5 years	• 1.5 T MRI and 3.0 T MRI performed on same day per patient (Seimens MAGNETOM MRI); scanner order balanced with 14 receiving 1.5 T MRI first and 14 receiving 3.0 T MRI first • 1 radiologist interpreter, blinded to patient and MRI strength; 50% of scans were viewed twice re intra-rater reproducibility	• Lesion count • Lesion volume • DIS	• 1.5 T MRI = 23/28 lesions; 3.0 T MRI = 25/28 lesions • 1 patient had DIS on 3.0 T MRI, but not 1.5 T MRI • 3.0 T MRI was more sensitive to hyper-intense brain lesions than 1.5 T MRI
MRI FOR PATIENTS WITH ESTABLISHED DIAGNOSIS OF MS: CLINICAL CORRELATION STUDY				

Table 12: Neurological Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to Clinical Situation**
Stankiewicz et al. 2009[13] United States Study years: NR Study funding: Lead author has GE funding	• n = 32 (+ 6 normal volunteers) • Inclusion criteria: MS or CIS with active disease (clinical relapse, new or enlarging MRI-defined CNS lesion, or EDSS increase ≥0.5 past year, (age 18 to 55 years • Patients: M/F, 8/24; mean age 42 (range 21 to 54); 26 with RRMS, 4 with SPMS, 1 with PPMS, 1 with CIS; median disease duration 5.8 years (range 0.2 to 29 years)	• 1.5 MRI and 3.0 T MRI of whole spinal cord performed a mean of 12 ± 11 days apart (range 0 to 49 days). • 2 interpreters (neurologists?) viewed anonymized, randomized images and came to consensus; findings confirmed by an experienced radiologist observer to resolve any discrepancies • Primary goal of the study was to determine correlation between 3.0 T MRI lesion burden and clinical measures rather than to directly compare 1.5 T MRI and 3.0 T MRI platforms.	*MRI FINDINGS:* • Lesion count • Lesion volume • DIS *CLINICAL:* • EDSS and spinal cord function • Pyramidal FSS Bladder & bowel FSS	• Correlation between MRI and clinical was weak (lesion count, volume, and DIS) and not improved with 3.0 T MRI • MRI not correlated with disease duration at T2 for 1.5 T MRI or 3.0 T MRI • 1.5 T MRI and 3.0 T MRI correlations between lesion volume and 25FW non-significant
MRI FOR PATIENTS WITH ESTABLISHED DIAGNOSIS OF MS				
Bachmann et al., 2006[8] Germany Study years: NR Study funding: NR	• 22 patients • Inclusion criteria: Clinically definite MS • Patients: M/F, 2/20; mean age 37 (range 22 to 64); 15 with RRMS, 5 with SPMS, 2 with PPMS; median disease duration 6 years (range 1 to 34 years); median EDSS score 3.3 (range 1 to 7.5)	• 1.5 T MRI and 3.0 T MRI performed per patient within 3 days • MRI were Philips Medical Systems • 2 blinded experienced radiologist interpreters (further details not provided)	• Optimal TE FLAIR for 3.0 T MRI	• 3.0 T MRI found more white matter lesions, plus improved visualization and image quality
Di Perri et al., 2009[11] United States and Italy Study years: NR Study funding: NR	• n = 41 (+ 38 normal controls) • Inclusion criteria: RRMS or SPMS, MRI at time of clinical visit, age 18 to 80 years, EDSS 0-8.5 • Patients: M/F, 9/32; mean age 47 (range 22 to 58); 32 with RRMS, 9 with SPMS; median disease duration 15 years (range 2 to 40 years); median EDSS score 3.7 (range 0 to 7)	• 1.5 T MRI and 3.0 T MRI performed in randomized order separated by < 7 days. • MRI were GE Healthcare Systems • 2 radiologist interpreters were blinded to clinical findings and MRI strength; viewed images independently and then came to consensus	• Lesion count • Lesion volume • DIS	• 3.0 T MRI showed higher number of lesions and greater volumes (P < 0.005) • Different spatial locations • Smaller signal abnormalities were missed on 1.5 T MRI

Table 12: Neurological Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to Clinical Situation**
Simon et al., 2010[14] Germany and The Netherlands 2009-2010 Study funding: Dutch Foundation for MS Research	• n = 34 (32 RRMS, 2 CIS) + 9 healthy controls • Inclusion criteria: CIS of CNS suggestive of MS or definite MS • Patients: M/F, 8/26; median age 38 (range 22 to 52) • Median disease duration: CIS, 6.5 months; MS 8 years • Median EDSS 1.6 (scale 0 to 4), indicating mild disability	• 1.5 T MRI and 3.0 T MRI performed within 12 hours per patient in randomized order (Philips MRI) • 2 radiologist interpreters with > 5 years of experience and expertise in neuro and MS imaging were blinded to clinical findings and MRI strength; viewed images together in random order to reach consensus	• Lesion count • Cortical vs. white matter lesions	• Increased number of cortical lesions seen on 3.0 T MRI (with dedicated DIR pulse sequence) versus 1.5 T MRI

25FW = timed 25-foot walk; CIS = clinically isolated syndrome (suggestive of MS); CNS = central nervous system; DIS = dissemination in space; EDSS = Expanded Disability Status Scale; FSS = functional system score; GE = General Electric; IV = intravenous; M/F = male / female; MRI = magnetic resonance imaging; MS = multiple sclerosis; NR = not reported; PPMS = primary progressive MS; RRMS = relapsing remitting MS; SPMS = secondary progressive MS; T = Tesla; w/ = with.

Table 13: Cerebrovascular Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to Clinical Situation**
CEREBROVASCULAR CONDITIONS (STROKE, ICA, CAROTID STENOSIS, AND INTRACEREBRAL STENOSIS)				
Kuhl et al., 2005[15] Germany Study years: NR Study funding: NR but authors stated no COI	• 25 patients • Inclusion criteria: Sx consistent w/ ischemic stroke and no evidence of cerebral hemorrhage • Patients: M/F, 16/9; median age 60 years (range 37 to 82); diagnosis acute stroke in 7, subacute in 18 • Mean interval from Sx to MRI, 82 hours (range 11 hours to 7 days)	• Each patient was imaged at 1.5 T MRI and 3.0 T MRI with imaging in random order • Mean interval between MRI was 32 minutes (range, 4 to 242 minutes) • MRI were Philips Medical Systems • 2 experienced neuroradiologists blinded to patient and type of MRI viewed images in random order and came to consensus	• Presence and number of ischemic lesions • Visualization of lesions (1 to 5 scale)	• No abnormality detected in 6 patients on 1.5 T MRI and 3.0 T MRI (these patients were considered to have had TIAs) • Of 48 lesions identified, 3.0 T MRI identified 47 (98%) and 1.5 T MRI identified 36 (75%). The additional lesions detected with 3.0 T MRI were small ischemic lesions (< 3 to 4 mm) in patients with multiple small ischemic infarcts that were also identified on the 1.5 T MRI images • 1 lesion identified on 1.5 T MRI but not 3.0 T MRI • Of 35 lesions identified by both 1.5 T MRI and 3.0 T MRI, visualization was SS greater in 3.0 T MRI, i.e., readers were more confident of the Dx
Anzalone et al., 2008[16] Italy Study year: 2002-2005 Study funding: NR	• n = 28 patients (29 ICAs) • Inclusion criteria: Patients receiving CE-MRA f/u for ICAs treated with GDCs • Patients: M/F, 11/17; mean age 58 (range 38 to 77) years	• Each patient was imaged first with unenhanced 3.0 T MRA, then with unenhanced 1.5 T MRA, then CE-MRA 1.5 T • MRI were Philips Medical Systems • Patient received all MRI within 24 hours • 2 interpreters viewed images in random order and reached consensus	• Visualization of residual patency of ICAs treated with GDCs	• Comparisons displayed are between 3.0 T MRI and CE-MRA 1.5 T MRI (excluded the plain 1.5 T findings as these were generally inferior): o 3.0 T = CE-MRA 1.5 T in detecting residual ICA (15/29) and the parent artery (29/29) o Preference was shown for 1.5 T MRI in 3/29 (10%) of cases versus 3.0 T MRI in 0 cases
Underhill et al., 2008[17] United States Study year: 2006 Funded in part by Pfizer; several	• n = 20 (one artery each) • Inclusion criteria: Asymptomatic adults with carotid stenosis (16% to 79%) as determined via DUS • Patients: M/F, 15/5; mean age 70 (range 50 to 86) years; smokers 50%; hypertensive 70%; diabetes 20%	• Order of MRI per patient NR • 1.5 T MRI, GE Healthcare; 3.0 T MRI, Philips • Mean time between MRI = 22 days (±26) • 2 teams of 2 radiologists blinded to field strength viewed images, reached consensus • From among the 20 index arteries imaged, there were 218 matched	• Presence or absence and area of plaque components	• 1.5 T MRI = 3.0 T MRI in identifying plaque components (calcification, lipid-rich necrotic core and hemorrhage) • 1.5 T MRI better at visualizing hemorrhage: 15% vs. 8% (P < 0.001) • Calcifications larger with 3.0 T MRI (P = 0.03)

Table 13: Cerebrovascular Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to Clinical Situation**
CEREBROVASCULAR CONDITIONS (STROKE, ICA, CAROTID STENOSIS, AND INTRACEREBRAL STENOSIS)				
authors employed by Pfizer		locations between 1.5 T MRI and 3.0 T MRI		
Buhk et al., 2010[18] Germany Study year: 2006 Study funding: German Research Foundation	• n = 27 patients • Inclusion criteria: Patients with Type 3 hyperlipoproteinemia (rare and known to be associated with atherosclerosis) • Patients: M/F, 18/9; mean age 59 (range 36 to 72) years	• Each patient was imaged with 1.5 T MRI and 3.0 T MRI within a few days of each other • MRI were Philips Medical Systems • 2 radiologists reviewed images independently	• Quality with respect to utility for diagnosis on a 1 to 5 scale (2 = questionable for Dx; 3 = adequate for Dx; 4 = more than adequate for Dx • Presence of pathology, including stenosis	• 1.5 T MRI = 3.0 T MRI for stenoses (3 detected) • Image quality mean scores with respect to Dx: 1.5 T MRI = 3.0; 3.0 T MRI = 3.7; P < 0.001. • Proportion scoring 2 (= questionable for Dx): 1.5 T MRI = 28%, 3.0 T MRI = 9% • Venous contrast overlay less common for 3.0 T: 1.5 T MRI = 26%; 3.0 T MRI = 11% • Insufficient coverage of the Circle of Willis: 1.5 T MRI = 30%; 3.0 T MRI = 11%

CE-MRA = contrast-enhanced magnetic resonance angiography; COI = conflict-of-interest; Dx = diagnosis; f/u = follow-up; GDC = Guglielmi detachable coils; GE = General Electric; ICA = intracranial aneurysm; M/F = male / female; MI = myocardial infarction; MRA = magnetic resonance angiography; MRI = magnetic resonance imaging; NR = not reported; SS = statistically significant; Sx = symptoms; T = Tesla; TIA = transient ischemic attack; vs. = versus; w/ = with.

Table 14: Renal Artery Stenosis: Included Study				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to Clinical Situation**
Herborn et al., 2008[19] United States Study years: 2004-2005 Study funding: NR	• n = 21 (45 renal arteries [3 had supernumerary arteries]) • Inclusion criteria: consecutive patients with hypertension of unknown origin referred for diagnosis or exclusion of renal arterial stenosis • Patients: M/F, 13/8; mean age 67 (range 45 to 77) years; mean blood pressure 150/94	• Exams with both MRI systems were performed at random > 24 hours apart (mean 25, max 29) • 1.5 T MRI and 3.0 T MRI were Siemens • Contrast agent 0.2 mmol/kg for 1.5 T MRI and 0.1 mmol/kg for 3.0 T MRI • 2 observers (blinded to patient) randomly assessed reduction of the luminal diameter for each renal artery lesion	• Detection of RAS	• 1.5 T MRI = 3.0 T MRI for detection of 5 renal artery stenoses • 1.5 T MRI with double dose of contrast) visualized overall vessel length and intraparenchymal branches better than 3.0 T MRI (with single dose of contrast)

M/F = male / female; MRI = magnetic resonance imaging; RAS = renal artery stenosis; w/ = with

Table 15: CAD Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to Clinical Situation**
Cheng et al., 2007[20] United Kingdom and United States Study years: NR Study funding: NR	• n = 65 (61 [94%] completed all imaging) • Inclusion criteria: Awaiting cardiac catheterization for suspected CAD (excluded if medically unstable or MI in previous 2 weeks) • Patients: M/F, 46/19; mean age 64 ± 8 years; mean CCS class 1.7; equal number of patients with single vessel disease, multiple vessel disease and no disease	• Each patient was imaged with cardiac MRI perfusion imaging at 1.5 T and 3.0 T on the same day, with imaging in random order • 1.5 T MRI and 3.0 T MRI were Siemens • 2 blinded observers viewed images in random order and reached consensus • All patients underwent cardiac catheterization within 2 weeks	• Diagnostic accuracy, sensitivity, specificity, PPV, NPV for detection of CAD • Detection of single vessel disease, multiple vessel disease, and overall CAD	• 3.0 T MRI superior to 1.5 T MRI for detection of single vessel disease and multi-vessel disease (both showed differences in area under ROC curve $P < 0.05$) • 1.5 T MRI = 3.0 T MRI for detecting CAD wrt ROC curve (0.87 vs. 0.78, P = 0.23) • Trend for 3.0 T MRI to be superior for detection of CAD (not SS) wrt diagnostic accuracy (90% vs. 82%), sensitivity (98% vs. 90%), specificity (76% vs. 67%), PPV (89% vs. 84%), NPV (94% vs. 78%)
Ligabue et al., 2008[21] Italy Study years: NR Study funding: NR	• n = 35 • Inclusion criteria: Consecutive patients previously treated with PTCA and stent implantation for acute MI • Patients: M/F, 33/2; mean age 64 ± 11 years	• Exams with both MRI systems were performed within 4 weeks of PTCA (mean 22 days, range 14 to 28) • 1.5 T MRI vs. 3.0 T MRI employed in random order and a mean of 7 ± 2 days apart • 1.5 T MRI and 3.0 T MRI were Phillips • 2 blinded observers viewed cine, perfusion and viability images	• Myocardial (LV) function and volumes • Myocardial viability assessment (presence and extent of perfusion defects and infarcted tissue)	• 1.5 T MRI = 3.0 T MRI in assessing functionality and viability parameters: ejection fraction, stroke volume, cardiac output, end diastolic volume, end systolic volume, wall motion score, perfusion score, scar score
Klumpp et al., 2009[22] Germany Study years: NR Study funding: NR	• n = 20 • Inclusion criteria: Chronic MI (excluding recent MI or cardiac intervention) • Patients: M/F, 19/1; mean age 60 ± 12 (range 33 to 75) years; past history of MI a mean of 944 days previous (range 93 to 7,253 days)	• Each patient was imaged with 1.5 T MRI and 3.0 T MRI in random order • MRI performed within 4 to 25 days • 1.5 T MRI and 3.0 T MRI were Siemens • 2 blinded radiologists viewed images in randomized order, 2 months later	• LV function • Size of MI • Confidence in diagnosis	• 1.5 T MRI = 3.0 T MRI for mean LV function (ejection fraction), extent and localization of MI or confidence in diagnosis

CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; LV = left ventricular; M/F = male / female; MI = myocardial infarction; MRI = magnetic resonance imaging; NPV = negative predictive value; NR = not reported; PPV = positive predictive value; PTCA = percutaneous transluminal coronary angioplasty; ROC = receiver operating characteristic; SS = statistically significant; T = Tesla; vs. = versus; w/ = with.

Table 16: Musculoskeletal Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to the Clinical Situation**
Schmid-Schwap et al., 2009[23] Austria Study years: 2006-2007 Study funding: NR	• n = 24 (both TMJs scanned = 48 images) • Inclusion criteria: Age > 18 years with TMJ clicking or suspected TMJ disc displacement • Patients: M/F, 5/19; mean age 35 ± 13 years	• Each patient was imaged at 1.5 T and 3.0 T with imaging in random order (MRI were Philips Medical Systems) • Time between imaging exams NR but assumed to be close together • 2 interpreters (dentist and radiologist) were blinded to patient, clinical findings and type of MRI and viewed images in random order completely independently	• TMJ disc shape • Signal intensity • Perceptibility of disc shape • Perceptibility of disc position	• Perceptibility of disc shape and disc position was reported as superior for 3.0 T MRI versus 1.5 T MRI for both reviewers; P < 0.001
Stehling et al., 2009[24] Germany Study years: NR Study funding: NR	• n = 21 • Inclusion criteria: acute wrist trauma • Patient descriptions: NR	• Each patient was imaged first at 3.0 T MRI, then at 1.5 T MRI (Philips Medical Systems) • Time between imaging exams NR but assumed to be close together • 3 interpreters (hand surgeon and 2 radiologists) were blinded to technical details and viewed images together in random ordered in a matched-pairs analysis, reaching consensus	• number of TFCC lesions • Visibility of anatomical structures (assessed via a 1 to 5 scale)	• Number of TFCC lesions: 11 on 1.5 T MRI and 14 on 3.0 T MRI • Visibility of anatomical structures: o Overall for TFCC: 3.0 T rated higher, P < 0.0001 o For cartilage delineation: 3.0 T rated higher, P < 0.002
CLINICAL CORRELATION STUDY				
Tagliafico et al., 2010[25] Italy Study years: 2009-2010 Study funding: Authors declare no COI	• n = 30 (+ 30 healthy volunteers) • Inclusion criteria: Adults with brachial plexus symptoms (dysthesia, paresthesia, or motor deficit) • Patients: M/F, 14/16; mean age 52 (range 19 to 65) years	• Each patient was imaged at 1.5 T MRI and 3.0 T MRI with imaging in random order (MRI were GE Healthcare) • Time between imaging exams < 1 week (mean 5 days, range 1 to 7 days) • 2 radiologists blinded to clinical condition and type of MRI viewed images independently in random order	• Visibility of nerve at 4 levels (1 to 4 scale) • MRI imaging diagnoses (confirmed by clinical follow-up, surgery, or pathologic analysis) • Pathologic findings	• Visibility of the nerve was superior for 3.0 T MRI versus 1.5 T MRI; p < 0.05 at all 4 levels • MRI imaging diagnoses showed no difference between 1.5 T MRI and 3.0 T MRI (including 9 tumours, 16 metastatic infiltration, and 2 fibre thickening) • Pathologic findings were seen equally well with 1.5 T MRI and 3.0 T MRI

COI = conflict-of-interest; M/F = male / female; MRI = magnetic resonance imaging; NR = not reported; NSD = no significant difference; T = Tesla; TFCC = triangular fibrocartilage complex; T = Tesla; TMJ = temporomandibular joint.

Table 17: Oncology Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to the Clinical Situation**
BREAST CANCER				
Kuhl et al., 2006[26] Germany Study years: NR Study funding: NR; 1 author employed by Philips Medical Systems	• n = 37 women (53 lesions: 25 breast cancer; 28 benign) • Inclusion criteria: contrast-enhanced lesion ON 1.5 T MRI • Patients: mean age 50 (range 30 to 69) years; clinical situations: 15 pre-op staging of biopsy-proven cancer, 9 equivocal mammogram or US, 6 familial breast CA screening, 5 f/u conservative treatment, 2 other	• Each patient was imaged first at 1.5 T MRI, then at 3.0 T MRI • Mean time between MRI was 2.4 days, median 1 day, range 1 to 9 days • MRI were Philips Medical Systems • 2 radiologists, blinded to biopsy and mammography findings (but not MRI strength) independently viewed images	• number of lesions identified • Diagnostic accuracy (ROC analysis)	• 49 lesions prospectively identified by both 3.0 T MRI and 1.5 T MRI; 2 additional lesions in 1 woman with 3.0 T MRI (staging of biopsy proven breast cancer) — her 1.5 T MRI scan was degraded by motion. • Improved classification of 10 of 51 total lesions in 9 of 35 patients. Differences in breast cancer staging between 1.5 T MRI and 3.0 T MRI but not in diagnostic labelling or management • Final management was decided on the basis of results from the 1.5 T MRI; 3.0 T MRI findings discussed with patients if discrepant from 1.5 T MRI • Greater diagnostic confidence at 3.0 T MRI (ROC analysis)
LIVER CANCER				
NO CLINICAL CORRELATION				
Kim et al., 2009[53] Japan Study year: 2006 Study funding: NR	• n = 22 • Inclusion criteria: Patients referred for MRI evaluation of focal lesions in the liver • Patients: M/F, 16/6; mean age 63 years (range 39 to 81); 16 with malignant liver tumours; underlying disease = 15 with chronic viral hepatitis or cirrhosis, 7 undiagnosed	• Each patient was imaged with both 1.5 T MRI and 3.0 T MRI in randomized order (time span between NR) • MRI GE Healthcare • 2 radiologists viewed images and reached consensus	• Tumour-to-liver contrast	• 1.5 T MRI and 3.0 T MRI equal in tumour-to-liver contrast • No significant difference in the relative SI of the liver, relative tumour contrast, image quality, or tumour visualization • This study did not discuss clinical correlation

Table 17: Oncology Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to the Clinical Situation**
INCLUDES CLINICAL CORRELATION				
Chang et al., 2006[27] Seoul, Korea Study years: 2004-2005 Study fund: NR	• n = 35 • Inclusion criteria: Focal liver lesions suspicious of malignancy (55 lesions: 15 hepatocellular cancers, 38 metastases, 2 other) Patients: M/F, 25/10; mean age 57 years	• Pre-contrast MRI was 1.5 T MRI (n = 23) or 3.0 T (n = 12), all patients received post-contrast 1.5 T MRI and 3.0 T MRI • 1.5 T MRI was Siemens, 3.0 T MRI was GEMS • 3 independent radiologists blinded to diagnosis • Lesion confirmation: biopsy (4), surgery (26), f/u testing (5)	• Diagnostic accuracy (ROC analysis)	• Diagnostic accuracy and sensitivity, 1.5 T MRI = 3.0 T MRI • No significant difference in detection of focal liver malignancies between 1.5 T MRI and 3.0 T MRI for any of the 3 radiologists; 2 metastases missed by all radiologists with 1.5 T MRI and 3.0 T MRI • 26 false positives on 1.5 T MRI and 3.0 T MRI
LIVER CANCER, INCLUDES CLINICAL CORRELATION (CONT.)				
Von Falken-hausen et al., 2006[28] Germany Study years: 2003-2004 Study funding: NR; 1 author employed by Philips Medical	• n=21 • Inclusion criteria: Patients referred for MRI evaluation of the liver (17 suspicious lesions, 4 f/u known lesions) Patients: M/F, 12/9; mean age 59 years (range 36 to 76); 79 focal liver lesions (benign and malignant)	• 1.5 T MRI then 3.0 T MRI within 3 to 7 days • 2 blinded radiologists independently compared randomized 1.5 T MRI and 3.0 T MRI images • Images read 2 months later by 2 different blinded radiologists • Liver lesions confirmed at biopsy (9) or subsequent surgery and testing (12); repeat MRI at 12 months for benign lesions (6)	• Diagnostic utility in terms of detection and characterization of focal liver lesions	• 76/79 lesions detected with 1.5 T MRI (missed 1 benign, 1 cyst, 1 metastasis seen with 3 T MRI only) vs. 77/79 lesions detected with 3.0 T MRI (missed 1 benign, 1 artifact) • 73/74 concordant classification on 1.5 T MRI and 3.0 T MRI (missed case was known gastric CA metastases) • Concluded that 3.0 T MRI diagnostic utility was at least as good as at 1.5 T MRI
Sofue et al., 2010[29] Japan Study year: 2007 Study funding: NR	• n = 28 (with 80 metastases) • Inclusion criteria: Hepatic metastases (≤ 10) on US or CT • Patients: M/F, 18/10; mean age 61 years (range 35 to 78); primary cancer: 24 colorectal, 4 other • Liver lesions biopsy-confirmed in 21/28 patients (46/80) lesions; 7/28 (34/80	• Pre-contrast 3.0 T MRI followed by post-contrast 1.5 T MRI on the same day • 1.5 T MRI was GEMS, 3.0 T MRI was Siemens • 3 radiologists assessed randomized images via 2 sessions, 2 weeks apart • 4th radiologist assessed correlation with histopathology or other test findings	• Lesion count • Lesion volume • Lesion location • sensitivity and PPV for the detection of hepatic metastases	• Diagnostic performance higher with 3.0 T MRI vs. 1.5 T MRI for all 3 observers on ROC analysis • Sensitivity higher for 3.0 T MRI versus 1.5 T MRI for all 3 observers (92, 91 and 90, versus 76,76, and 81, respectively) resulting in higher observer performance in detecting metastases • PPV equal • 7 false positives on 1.5 T MRI and 3.0 T fMRI or all 3 observers (2 lesions misdiagnosed as metastases on 1.5 T MRI and 3.0 T MRI by 2 observers) • False negatives 1.5 T MRI = 3.0 T MRI

Table 17: Oncology Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to the Clinical Situation**
	lesions) confirmed re f/u growth			
PROSTATE CANCER				
Beyersdorff et al., 2005[30] Germany Study year: NR Study funding: NR	• n=24 • Inclusion criteria: Biopsy-confirmed prostate cancer for pre-op staging • Patients: Mean age 62 years (range 50 to 72) • 22/24 had radical prostatectomy (surgery d/c for 1 due to disseminated cancer, other had no surgery as disease was benign)	• 3.0 T MRI (routine pre-op) followed by 1.5 T MRI; both performed same day for 17/24 patients, up to 7 days for remaining 7 • 1.5 T MRI was Siemens, 3.0 T MRI was GEMS • 1.5 T MRI with endorectal coil; 3.0 T MRI with torso coil • 2 independent radiologists NOT blinded (coil visible) • Tumour staging: confined to prostate or outside the capsule (determines surgical versus non-surgical treatment)	• Tumour localization, extracapsular extension, and infiltration of adjacent organs • TNM staging • Retroanalysis for image quality, tumour delineation and visualization of staging criteria	• 1.5 T MRI showed better delineation of capsule, tumour and zonal anatomy • 1.5 T MRI showed better sensitivity and specificity for assessing capsular infiltration • 1.5 T MRI and 3.0 T MRI showed 73% accuracy for local staging • 1.5 T MRI = 3.0 T MRI for TNM staging
Torricelli et al., 2006[31] Italy Study years: 2004-2005 Study funding: NR	• n = 29 • Inclusion criteria: Biopsy-confirmed prostate cancer for pre-op staging • Patients: Mean age 66 years (range 57 to 75) • 22/29 had radical prostatectomy	• 1.5 T MRI and 3.0 T MRI within 1 week (> 30 days post-biopsy) • MRI were Philips Medical System • 2 radiologists independent for image quality, consensus for tumour extent • tumour staging: confined to prostate or outside the capsule (determines surgical versus non-surgical treatment)	• Sensitivity, specificity, PPV, NPV for extra-capsular tumour invasion	• 1.5 T MRI = 3.0 T MRI for sensitivity (0.75 vs. 0.83), specificity (both 0.90), PPV (both 0.90), NPV (0.75 and 0.81) • 1.5 T MRI image quality better in evaluating tumour visualization, capsular infiltration, and seminal vesicle involvement • No change in cancer staging or treatment based on 1.5 T MRI vs. 3.0 T MRI
ENDOMETRIAL CANCER				
Hori et al., 2009a[32] Japan Study years: 2006-2007 Study funding: NR	• n = 30 • Inclusion criteria: Women suspected of having endometrial CA; MRI used for pre-op evaluation • Patients: Mean age 59 years (range 43 to 79); 6 (20%) pre- and 24 (80%)	• Patients received 1.5 T MRI and 3.0 T MRI within 30 minutes (random order) • MRI GE Healthcare • 2 blinded radiologists (not blinded for patient age) assessed images for extent of invasion and metastasis and scored them on a 5-point scale	• Sensitivity, specificity, PPV, NPV, diagnostic accuracy for myometrial and cervical invasion plus lymph node metastases • Gold standard	• Local regional staging was not significantly different between 1.5 T MRI and 3.0 T MRI o Myometrial invasion o Cervical invasion o Lymph node metastasis • 1.5 T MRI = 3.0 T MRI for sensitivity, specificity, PPV, NPV for both readers for all comparison pairs

Table 17: Oncology Conditions: Included Studies				
Study	**Patient Population**	**Imaging Procedure**	**Relevant Outcomes**	**Findings Relevant to the Clinical Situation**
	post-menopausal • All had TAH 1 to 57 days (mean 28) after MRI; 21 also had pelvic lymphadenectomy		pathology findings at surgery	
CERVICAL CANCER				
Hori et al., 2009b[33] Japan Study years: 2006-2007 Study funding: NR but authors stated no COI	• n = 31 • Inclusion criteria: Women with biopsy-proved untreated cervical carcinoma; MRI used for pre-op evaluation • Patients: Mean age 51 years (range 27 to 71) • All had hysterectomy 13 to 75 days (mean 34) after MRI; 27 also had lymphadenopathy	• Patients received 1.5 T MRI and 3.0 T MRI within 30 minutes (random order) • MRI GE Healthcare • 2 blinded radiologists (not blinded for patient age) assessed images for extent of invasion and metastasis and scored them on a 5-point scale	• Sensitivity, specificity, PPV, NPV, diagnostic accuracy for parametrial, and vaginal invasion plus lymph node metastases • Gold standard pathology findings at surgery	• Local regional staging was not significantly different between 1.5 T MRI and 3.0 T MRI o Parametrial invasion o Vaginal invasion o Lymph node metastasis • 1.5 T MRI = 3.0 T MRI for sensitivity, specificity, PPV, NPV for both readers for all comparison pairs

CA = cancer; COI = conflict of interest; f/u = follow-up; d/c = discontinued; GEMS = General Electric Medical Systems; M/F = male/female; MRI = magnetic resonance imaging; NPV = negative predictive value; NR = not reported; PPV = positive predictive value; ROC = receiver-operating characteristic; SI = signal intensity; TAH = total abdominal hysterectomy; T = Tesla; TNM staging = tumour, nodes, metastases; US = ultrasound; w/ = with; w/in = within.

APPENDIX 4: EXAMPLES OF MRI TECHNICAL TEST PARAMETERS

Technical test parameters were reported in many of the included studies but were not summarized, as the systematic review analysis focussed on clinical impact.

Diagnostic accuracy

- Inter-rater comparison of accuracy at 1.5 T MRI and 3.0 T MRI using the alternative-free response receiver operating method.
- Receiver operating characteristic (ROC) curves were fitted to each reader's confidence ratings using a maximum-likelihood estimation.
- Each observer's performance for detecting focal lesions or pathology with each imaging technique was assessed using the area under the ROC curves.
- Differences between ROC curves were determined using a univariate z score test ($p < 0.05$ was considered to be statistically significant).

Technical test parameters (quantitative and qualitative)

A. Quantitative

- Signal-to-noise ratio (SNR)
- Contrast-to-noise ratio (CNR)
- Signal intensity usually measured in an operator defined region of interest

B. Qualitative

- Image artifact; susceptibility, motion, dielectric, chemical shift
- Image quality
- Image visualization

SUPPLEMENTAL ISSUES

Review and Critical Appraisal of Guidelines

One goal was to locate evidence-based clinical practice guidelines (CPGs) that addressed indications for 1.5 T MRI and 3.0 T MRI. Although CPGs exist for MRI indications in general, no evidence-based CPGs commented on different indications based on magnet strength of MRI.

Planning for 3.0 T MRI versus 1.5 T MRI

This material presents considerations when replacing a 1.5 T MRI scanner with a 3.0 T MRI scanner. The examples used are specific to the Siemens 1.5 T MAGNETOM Aera and 3.0 T Skyra devices, and the material was drawn from Siemens Aera and Skyra planning guides (Brent Oram, Siemens Canada Limited, unpublished data, 2010).

Room size

The 3.0 T device is a larger machine. The 1.5 T Aera is 145 cm cover to cover. The 3.0 T Skyra is 173 cm. Therefore, the 3.0 T Skyra requires a longer room (recommended room sizes are 1.5 T Aera, 351 cm x 662 cm; Skyra, 351 cm x 676 cm).

Magnet weight

The 3.0 T Skyra is a heavier machine by 57%: 1.5 T Aera, 4578 kg; 3.0 T Skyra, 7100 kg. Also, if the MRI system is not located on grade, consideration must be given to structural support.

Magnetic shielding

The fringe field around an MRI magnet can activate pacemaker switches or controls. Such activations are a safety risk. Areas with magnetic fields higher than 5 Gauss (0.5 mT or 0.0005 T) commonly have restricted access and are designated as a risk to people with pacemakers. Therefore, the magnetic shielding in the scan room walls must confine the 5 Gauss fringe field in the scan room. The fringe field of the 3.0 T Skyra extends further in all three directions compared to the 1.5 T Aera and therefore sufficient steel must be installed in the cabin walls. More information is available at:
http://www.koppdevelopment.com/articels/outside_bore.htm.

Fringe field distribution

The following tables show that the fringe field distribution for the 3.0 T MRI is larger in all three dimensions (X axis, Y axis, and Z axis) than it is for the 1.5 T MRI.

Aera 1.5 T MRI

Fringe Field distribution MAGNETOM Aera			
Fringe field	Distance from magnetic center in direction of		
	X axis	Y axis	Z axis
20mT	1.4	1.4	2.0
10mT	1.5	1.5	2.2
5mT	1.7	1.7	2.5
3mT	1.8	1.8	2.8
1mT	2.2	2.2	3.4
0.5mT	2.5	2.5	4.0
0.15mT	3.1	3.1	5.2
0.1mT	3.3	3.3	5.7
0.05mT	3.9	3.9	6.7

Skyra 3.0 T MRI

Fringe field distribution MAGNETOM Skyra			
Fringe field	Distance from magnetic center in direction of		
	X axis	Y axis	Z axis
20mT	1.6	1.6	2.2
10mT	1.8	1.8	2.5
5mT	1.9	1.9	2.9
3mT	2.1	2.1	3.2
1mT	2.3	2.3	4.0
0.5mT	2.6	2.6	4.6
0.15mT	3.4	3.4	6.1
0.1mT	3.8	3.8	6.8
0.05mT	4.9	4.9	8.2

Wave guides

Wave guides (ports through which intravenous tubing or other lines may be passed through into the scan room) specific for 1.5 T scanners must be replaced with new wave guides for 3.0 T.

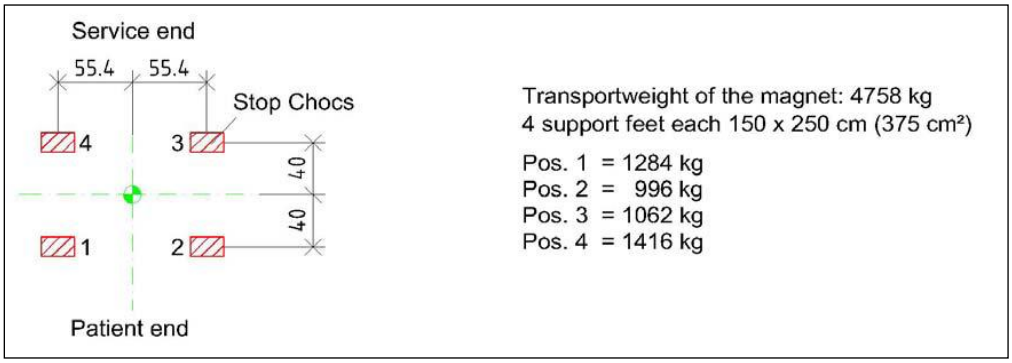
Radiofrequency shielding

The radiofrequency shielding is usually not replaced when installing a 3.0 T MRI. An SNR check determines whether the radiofrequency shield has deteriorated over time and therefore needs repair or replacement.

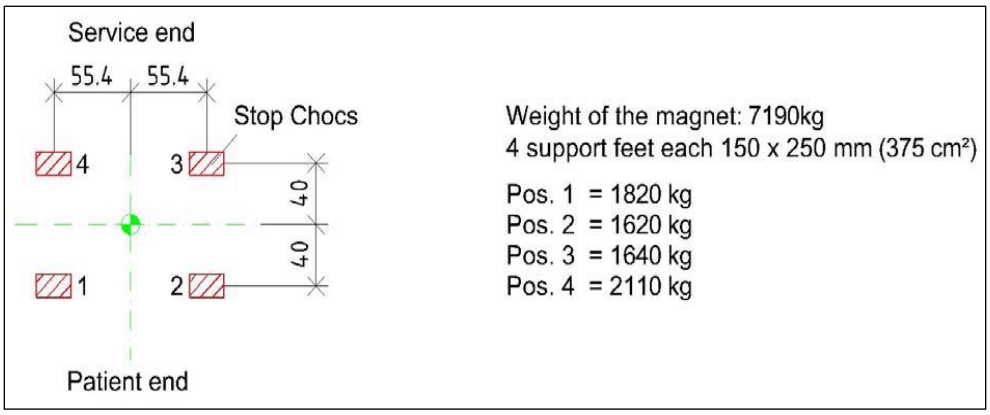
Floor loading

Floor loading at each of the support feet is increased in the four positions for the 3.0 T Skyra compared to the 1.5 T Aera, with area requirements and floor loading for the magnet shown here.

Aera 1.5 T MRI



Skyra 3 T MRI



MRI Cost Table

Based on the information provided by one vendor, Appendix 1 Table 10 shows the cost for a basic 1.5 T MRI, the cost for the same 1.5 T MRI device with partial upgrading, and the cost for the same 1.5 T MRI device fully loaded. The magnitude of the cost difference is shown between the basic 1.5 T MRI and the fully loaded 1.5 T MRI. The same was done for the 3.0 T MRI device. In the right-hand columns of Table 10, the magnitude of cost difference is shown for a fully loaded 1.5 T MRI compared with a 3.0 T MRI.

Safety in Infants, Pediatric Populations, and Adults

Objective

The purpose of this supplemental issue was to review the literature on the safety of 1.5 T and 3.0 T MRI in infants, pediatric populations, and adults (including geriatrics). Particular attention was paid to patients with implanted medical devices such as pacemakers, defibrillators, deep brain stimulators, and stents.

Methods

Relevant articles reporting on safety outcomes were identified from the clinical literature search for the main report. In addition, a focused search was conducted in PubMed for articles in which the main concepts appeared in the title or as a major subject heading. The search was limited to English or French language documents published between January 1, 2005 and February 11, 2011. No filters were applied to limit retrieval by study type.

Studies were eligible for inclusion if they met the criteria outlined in Table 1. Simulation studies performed on "phantoms," cadavers, or animals were excluded. Data were extracted from the studies that met the inclusion criteria and were summarized in evidence tables and discussed narratively.

Table 1: Selection Criteria for Safety Studies on 1.5 T MRI and. 3.0 T MRI

Study details	• Published in English or French • Published from January 1, 2005, onward • Individual case studies were excluded • No other restriction on study design or number of participants enrolled
Population	• Adults patients or healthy volunteers with implanted medical devices undergoing MRI (e.g., pacemakers, defibrillators, cochlear implants, vagus nerve stimulators, stents, deep brain stimulators, surgical clips, pumps) • Adult patients or healthy volunteers without implanted medical devices undergoing MRI • Infants, pediatric patients, or healthy volunteers with or without implanted medical devices undergoing MRI • Studies with mixed populations (infants, pediatric patients, adults) were also included
Intervention	• 1.5 T MRI or 3.0 T MRI
Comparators	• 1.5 T MRI or 3.0 T MRI • No comparator
Outcomes	• Any measure of safety

MRI = magnetic resonance imaging; T= tesla

Results

a) Study Characteristics

Of the 910 citations identified in the literature searches, a total of 18 relevant non-randomized studies met the inclusion criteria for adults, infants, and children. The characteristics of the included studies (number of patients, inclusion criteria, MRI scanner used, safety outcomes assessed) are summarized in Table 2.[54-71] Three of these studies evaluated the safety of 1.5 T MRI or 3.0 T MRI in infants and pediatric patients.[54-56] Of the remaining 15 studies performed in populations not restricted to pediatric patients, the vast majority assessed the safety of implanted cardiac devices during MRI. Five studies evaluated the safety of 1.5 T MRI or 3.0 T MRI in patients with cardiac stents,[57-61] five studies evaluated the safety of 1.5 T MRI in patients with pacemakers or implanted cardioverter-defibrillators,[62-66] and one study assessed 3.0 T MRI in patients with implanted cardiac monitors.[67] The safety 1.5 T MRI or 3.0 T MRI in patients with deep brain stimulators was evaluated in two studies,[68,69] cochlear implants in one study,[70] and an implanted spinal infusion pump in one study.[71] Sample sizes ranged from 16 to 249 patients.

Most studies evaluated the safety of implanted devices in series of consecutive patients undergoing 1.5 T MRI and did not have control groups. Two studies compared the safety of 1.5 T MRI to 3.0 T MRI, one in infants[56] and one in cardiac stents.[59] Two studies assessed the safety of 3.0 T MRI, one in cardiac stents[57] and one in patients with implanted cardiac monitors.[67]

b) Safety Outcomes

Safety outcomes of the included studies and the authors' conclusions are summarized in Table 2.

Infants and pediatrics

The three studies in infants and pediatric patients evaluated the safety of MRI in quite different populations: very low birth weight (VLBW) infants,[54] neonates who were exposed to MRI in utero,[55] and infants and children undergoing cranial MRI.[56] In VLBW infants, no significant changes were observed in heart rate, oxygen saturation, or body temperature following 1.5 T MRI.[54] Conversely, in a group of pediatric patients with an average age of about four years, 1.5 T MRI and 3.0 T MRI were both associated with increases in core body temperature.[56] In the third study, second and third trimester exposure to 1.5 T MRI was not clearly associated with hearing loss or cochlear impairment in neonates.[55]

One relevant non-randomized comparative study[72] was identified through the alert process from the systematic review. The authors concluded that 3.0 T MRI did not result in increased body core temperature (as defined as more than a 0.5 degrees Celsius change) in 400 patients aged 21 years or younger.

Cardiac stents

Low rates of complications in patients with cardiac stents who underwent 1.5 T MRI or 3.0 T MRI was demonstrated in five studies.[57-61] Outcomes assessed included tolerance and complications during the MRI, death, and other cardiovascular events following the MRI, and stent patency. In two studies that assessed 3.0 T MRI, no complications directly attributable to the MRI were observed (e.g., stent patency, stent migration, complications during MRI, cardiac events following MRI).[57,59] Similarly, in 1.5 T MRI no major safety issues were encountered.[58-61]

Cardiac pacemakers and implantable cardioverter-defibrillators
All the included studies of pacemakers and implantable cardioverter-defibrillators evaluated the safety of the devices when undergoing 1.5 T MRI.[62-66] The impact of MRI on the functioning of the device itself and on the patient were assessed in four of the five studies.[63-66] One study assessed only ectopic beats and found that a minority of patients with pacemakers will experience ectopic beats following 1.5 T MRI.[62] There were no patient-reported symptoms of torque, heating, or movement of the device in the studies that assessed this outcome.[65,66] No changes in programming parameters were observed in two studies,[64,66] but, in a third study, there were seven cases where the programmed settings of the pacemaker reset to different values.[65] Changes in pacing capture thresholds were noted in two studies.[63,65] Generally, authors of the studies concluded that 1.5 T MRI could be safely performed under the specific conditions of the study, in patients with the devices that were specifically assessed in the studies.

Implantable cardiac monitor
One study assessed the safety of an implantable cardiac monitor in patients undergoing 3.0 T MRI.[67] This study will be completed in 2011; however, preliminary findings suggest no patient adverse events (heating sensation, palpitations, paresthesia, device movement) or effects on the device itself (battery status, programming, activation, and recording of data).

Deep brain stimulators
Two studies assessed the effect of 1.5 T MRI on the functioning of deep brain stimulators.[68,69] No adverse effects on the patient were noted in either study.[68,69] In a study of 249 patients, 16 cases of device malfunction were noted but were not clearly related to the MRI.[69] Both studies concluded that 1.5 T MRI was safe under the study conditions and device configurations that were used.

Cochlear implants
One study assessed the safety of 1.5 T MRI in patients with cochlear implants.[70] For the procedure, the devices were bound to prevent or minimize movement. Patients experienced mild discomfort during the MRI, but there were no cases of the device being displaced. In one of 16 cochlear implants, the magnet of the device was affected by MRI.

Implanted spinal infusion pump
One study assessed the safety of 1.5 T MRI in patients with implantable spinal infusion pumps that were not turned off or emptied during MRI.[71] There were no adverse events (patient or pump) associated with 1.5 T MRI.

Limitations

The majority of the included literature assessed the safety of 1.5 T MRI. Few studies compared the safety of 3.0 T and 1.5 T MRI in pediatric patients or patients with implanted medical devices, or assessed the safety of 3.0 T MRI in a single group of patients.

The majority of included studies did not have comparison or control groups, which increases the risk of confounding the study results. Further, the study populations and devices were often carefully selected to reduce the risk of adverse effects, which could limit the generalizability of the findings to the broader population with implanted devices. Moreover, the studies often

employed strict safety protocols to minimize harm. In the absence of such protocols, the risk to patients and devices could be different from what was observed under the study conditions. As well, the sample sizes tended to be small (15 of 18 studies had fewer than 100 patients), which could limit the ability to detect rare adverse events.

Authors of the studies stressed that their results would not be generalizable to other models of the implanted medical devices examined in the studies, other models of MRI scanners, different magnet strengths (higher or lower, as higher strengths could create higher torque and lower strengths could interfere with device signals), and other scan sequences. In addition, MRI was performed on specific regions of the body. Scanning regions closer to the implanted device could alter the safety.

Individual case reports could provide additional safety data on specific devices and MRI conditions; however, these reports were not included in this report. These case reports may provide an indication of device safety when patients are not carefully screened and strict safety protocols are not adhered to. As well, simulation or experimental studies could provide preliminary safety data and help to identify potentially unsafe devices. Such studies would not, however, guarantee safety in patients.
A number of studies did not report patient characteristics, making it difficult to determine if the populations included geriatrics and pediatrics. Further, no study restricted the population to geriatrics. Thus, the generalizability of the results to specific age groups, such as those over the age of 65, is unclear. Additional safety concerns in older adults may be warranted in this population.

Conclusions

There is some evidence that 1.5 T MRI can be safely performed in patients implanted with stents, pacemakers, implantable cardiac defibrillators, deep brain stimulators, cochlear implants, and spinal infusion pumps under conditions and safety protocols identical to those used in the identified studies. Safety cannot be generalized to other conditions. Further, methodological limitations of the studies should be considered in interpreting their results. One study suggests that the core temperature of children may be increased with 1.5 T MRI and 3.0 T MRI scanning. The authors of this study suggested continuous monitoring of temperature during MRI, especially in children with fever or who were critically ill, but did not discuss these findings in relations to the risk of burns. A subsequently identified study concluded that 3.0 T MRI was not associated with an increased change in temperature in a pediatric population. Initial evidence suggests that 3.0 T MRI may be safe with cardiac stents under the same conditions as those used in the studies, but this was observed in only two studies with methodological limitations. One specific model of an insertable cardiac monitor may also be safe with 3.0 T MRI.

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
INFANTS AND PEDIATRICS				
Benavente-Fernández et al., 2010[54] Spain Study year: 2008 Study funding: NR	n= 33 premature VLBW infants in an NICU (46 MRI scans) Inclusion criteria: • VLBW infants who underwent MRI as part of a preterm brain injury study Patients: M/F: 23/10 Mean gestational age at birth: 30 weeks (range 25 to 33)	• 1.5 T MRI (MAGNETOM Sonata, Seimans)	Heart rate Oxygen saturation Body temperature Blood pressure	No significant changes during transport, during MRI, and following the procedure for any of the outcomes. Authors' conclusions: MRI is a safe procedure in VLBW infants.
Reeves et al., 2010[55] United Kingdom Study years: 1999 to 2007 Study funding: NR	n = 103 neonates Inclusion criteria: • Neonates who were born to women who underwent in utero MRI examinations during the study period Patients: M/F: 58/45 Median gestational age at exposure: 24 weeks (range 16 to 40)	• 1.5 T MRI with Marconi/Philips Eclipse or Infinion ; or MAGNETOM Avanto	Otoacoustic emission test	One infant had bilateral hearing loss. Cochlear response in infants exposed to MRI in utero was lower (P = 0.002) at one of four frequencies (4 kHz) than a group of unexposed reference infants. No difference in cochlear response at 4kHz when the analysis was restricted to well babies. Authors' conclusions: There is some evidence that second and third trimester exposure to 1.5 T MRI does not lead to substantial cochlear injury or hearing impairment in neonates.

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
Machata et al., 2009[56] Vienna Study year: 2008 Study funding: NR	n = 76 consecutive infants and children undergoing cranial MRI during a 3-month period Inclusion criteria: • ASA status I or II 1.5 T MRI patients: M/F: 20/18 Mean age: 3.9 years (range 1.4 to 4.5) 3.0 T MRI patients: M/F: 16/22 Mean age: 3.8 (range 2.3 to 4.4)	• 1.5 T MRI (Philips Intera) • 3.0 T MRI (MAGNETOM Trio TIM)	Body temperature (degrees Celsius)	1.5 T MRI tympanic temperature Median pre-scan: 37.0 Median post-scan: 37.2 P < 0.001 1.5 T MRI rectal temperature Median pre-scan: 36.9 Median post-scan: 37.1 P < 0.001 3.0 T MRI tympanic temperature Median pre-scan: 37.0 Median post-scan: 37.5 P < 0.001 3.0 T MRI rectal temperature Median pre-scan: 37.0 Median post-scan: 37.5 P < 0.001 All patients sweated following the procedure. Authors' conclusions: Clinicians should consider that temperature may increase with MRI. Body temperature should be continuously monitored, particularly for patients with fever and/or who are critically ill.
ADULTS OR MIXED POPULATIONS				
CARDIAC STENTS				
Jehl et al., 2009[57] France Study years: 2005 to 2006 Study funding: NR	n = 72 patients Inclusion criteria: • Patients with acute MI who underwent PCI with stenting and had CMR performed. Patients M/F: 61/11 Mean age: 55 ± 10.6 years	• 3.0 T MRI (GE Healthcare Signa HD) performed an average of 6.5 days following stenting.	Major cardiac adverse events (death, MI, repeat revascularization) Tolerance and complications during imaging	No complications during imaging, no stent thrombosis. No deaths, MI, TIA, or stroke six months following imaging. Four reports of unstable angina, five patients required repeat procedures.

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
				Nine patients had repeat angiograms. No stent migration noted on these. Authors' conclusions: 3.0 T MRI can be safely performed shortly after coronary artery stenting.
Kaya et al., 2009[58] Turkey Study years: 1998 to 2005 Study funding: NR	n = 43 patients (45 MRI scans) Inclusion criteria: • Patients who underwent coronary artery stenting and had MRI performed within 8 weeks (early term) or more than 8 weeks (late-term) Patients M/F: 28/15 Mean age: 63 ± 10 years	• 1.5 T MRI with Signa (GE Medical Systems)	MACE: Combined end point of death, nonfatal MI, revascularization, cerebrovascular events	Combined end point: Early-term: 41% Later-term: 23% P = 0.20 No statistical differences in the individual end points. Authors' conclusions: MRI can be safely performed following coronary artery stenting and was not associated with an increased risk of MACE in the early or later-term groups.
Nijveldt et al., 2008[59] The Netherlands Study years: NR Study funding: The Netherlands Heart Foundation Grant	n = 25 consecutive patients (36 CMR studies) Inclusion criteria: • Admitted for acute first STEMI • Successful primary PCI with stent implantation Patients: M/F: 21/4 Mean age: 55 ± 9 years	• 18 scans with 1.5 T MRI (MAGNETOM Sonata, Siemens) • 18 scans with 3.0 T MRI (Intera, Phillips)	Patient reported discomfort, symptoms Clinical events Stent position and patency for patients undergoing repeat procedures (e.g., catheterization)	No patient reported discomfort, symptoms with 1.5 T MRI or 3.0 T MRI imaging. No clinical events during or shortly after 1.5 T MRI or 3.0 T MRI imaging. No difference in stent patency and position compared to initial result with 1.5 T MRI or 3.0 T MRI imaging. Authors' conclusions: Safe to perform 3.0 T MRI scanning following MI in patients treated with primary stenting.
Syed et al., 2006[60] United States Study years: 2002 to 2004 Study	n = 119 consecutive patients, 51 who underwent CMR and 68 controls Inclusion criteria: • Patients with acute STEMI who presented to a community hospital emergency room and	• 1.5 T MRI with Signa CV/i (GE Medical Systems)	Death from any cause, MI, acute coronary syndrome requiring hospitalization, congestive heart failure, and coronary	Total number of events higher in the group who did not undergo CMR (16.9% of patients versus 4.3%). No difference in death, reinfarction, stent thrombosis, re-stenosis, or heart failure.

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
funding: National Institutes of Health	underwent primary PCI with bare-metal stent implantation during the study period • Chest pain of less than 12-hour duration associated with segment elevation on electrocardiogram Patients: M/F: 88/31 Average age: 66.0 ± 13.5		angiography performed for clinical indications	ACS was higher in the group who did not undergo CMR. Authors' conclusions: CMR on a 1.5 T MRI scanner can be safely performed in stable patients 1 to 7 days after primary PCI with bare-metal stent implantation, and is not associated with an increased risk of adverse clinical cardiac outcomes.
Patel et al., 2006[61] United States Study years: 2002 to 2004 Study funding: None	Study group (MRI): 66 patients Control group (no MRI): 124 patients Inclusion criteria: • Patients with acute STEMI and non-STEMI who had undergone stent implantation Patients: M/F: 144/46 Median age: 57 (interquartile range: 49 to 65)	• 1.5 T MRI (Sonata, Siemens) performed a median of 3 days following stent implantation	Combined end point of death, MI, repeat revascularization	Combined end point (30 days) Study group – 2% Control group – 6.5% P = 0.13. No differences for individual outcomes (death, MI, repeat revascularization). Authors' conclusions: MRI shortly after acute MI and stenting appeared to be safe for the stent types under the conditions of the study.
CARDIAC PACEMAKERS OR DEFIBRILLATORS				
Mollerus et al., 2009[62] United States Study years: not reported Study funding: Duluth Clinic Foundation	n = 52 patients (59 MRI examinations) Inclusion criteria: • Patients with pacemakers or ICDs who underwent a medically necessary MRI scan • Device in place for at least 6 weeks at the time of the scan • Sinus rhythm during the pre-scan evaluation Patients: Characteristics not reported.	• 1.5 T MRI with Siemens Symphony	Ectopic beats	7 patients had significant ectopy observed. 1 patient had atrial fibrillation Authors' conclusions: A minority of patients with pacemakers undergoing MRI may have MRI-related ectopy.

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
Naehle et al., 2009[63] Germany Study years: 2000 to 2008 Study funding: No funding	n = 47 patients (171 MRI examinations) Inclusion criteria: • Urgent need for MRI • Stable physical and pacing pacemaker parameters • At least 3 months since pacemaker and lead implantation Patients: Characteristics not reported	• 1.5 T MRI (Intera,, Phillips) • Safety protocol in place to maximize safety	Atrial pacing capture threshold Ventricular pacing capture threshold Atrial and ventricular lead impedance Battery voltage	Small but significant decrease in atrial pacing and ventricular capture thresholds and battery voltage with increasing number of MRI examinations performed. Atrial and ventricular lead impedance: no significant relationship to number of MRI. Authors' Conclusions: Although no clinically relevant changes were noted in the safety outcomes with repeat MRI, careful risk versus benefit analysis is needed for patients with pacemakers undergoing MRI.
Mollerus et al., 2008[64] United States Study years: not reported Study funding: Duluth Clinic Foundation	n = 37 patients (40 MRI examinations) Inclusion criteria: • Patients with pacemakers or ICDs who underwent a medically necessary MRI scan • Device in place for at least 6 weeks at the time of the scan Patients: Characteristics not reported	• 1.5 T MRI with Siemens Symphony	Pacing threshold (aggregate of right atrial, right ventricular, and sinus leads) Cardiac enzymes Device malfunction	No device resetting or programming changes observed. No effect on battery. Cardiac enzymes unchanged pre- and post-MRI. Capture threshold remained unchanged. Authors' conclusions: MRI scan may be performed safely in appropriately selected patients with close monitoring.
Sommer et al., 2006[65] Location unclear Study years: not reported Study funding: Medtronic	n = 82 patients (115 MRI examinations) Inclusion criteria: • Patients with pacemakers who were in need of urgent non-thoracic MRI • Patients were not pacemaker- dependent • Medtronic pacemaker manufactured between 1993 and 2004 • Stable pacemaker,	• 1.5 T MRI (Interaf, Phillips)	Heart rate, oxygen saturation, heat or torque sensation, pain, dizziness Pacing capture thresholds Serum troponin	No reports of heat or torque sensation, pain, dizziness. In 7 exams, the pacemaker reset with alterations in the programmed parameters. No changes in heart rate or rhythm. Statistically significant changes in pacing capture thresholds, the magnitude of

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
	physical parameters • > 3 months since implantation of pacemaker and leads Patients: M/F: 53/29 Average age: 66.9 (range: 3.9 to 88.5)			which was clinically important in 6 patients. Decrease in lead impedance and battery voltage (statistically significant). No statistically significant change in troponin overall. 4 patients had troponin increase from normal at baseline to above normal following MRI. Authors' conclusions: Non-thoracic MRI can be safely performed under controlled conditions in patients with pacemakers who are not pace-maker dependent. However, the authors also state that safety cannot be guaranteed.
Nazarian et al., 2006[66] United States Study years: 2003 to 2005 Study funding: National Institutes of Health	n = 55 patients (68 MRI examinations) Inclusion criteria: • Patients with permanent pacemakers or ICDs who required MRI • No acceptable imaging alternative • Device found to be safe in previous phantom studies (simulation/experimental condition) • > 6 weeks since implantation Patients: Characteristics not reported	• 1.5 T MRI with Signa CV/i, (GE Medical Systems) • Safety protocol also followed	Battery voltage, lead impedance, lead thresholds, sensing signal amplitudes Patient symptoms of torque, heating, device movement	No reported symptoms of torque, heating, device movement. No changes in device programming following MRI. No individual or mean level changes in battery voltage, lead thresholds, lead impedance, or sensing signal amplitudes Authors' conclusions: MRI can be safely performed in the presence of implanted cardiac devices under the safety protocol used in the study.
IMPLANTED CARDIAC MONITOR				
Haeusler et al., 2010[67] Germany Study years: 2009 to 2011 (in progress)	n = 24 patients with 62 MRI (preliminary results — study in progress) Inclusion criteria: • Patients implanted with the Reveal XT Insertable Cardiac	• 3.0 T MRI (Tim Trio, Siemens)	Patient adverse events Device battery status, programming, activation and storage of data	No reports of heating sensation, palpitations, paresthesia, movement of device. No changes in device battery status, orginal device programming,

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
Study funding: Center for Stroke Research Berlin	Monitor who underwent MRI M/F: 15/9 Median age: 65 (range: 42 to 77)			activation, and storage of data to record abnormal cardiac rhythm. No loss of previously recorded data. Authors' conclusions: 3.0 T MRI is safe for patients with the Reveal XT.
DEEP BRAIN STIMULATORS				
Fraix et al., 2010[68] France Study years: 2000 to 2008 Study funding: NR	n = 31 patients (61 MRI examinations) Inclusion criteria: • Patients who received DBS hardware for movement disorders during the study period Patients: Characteristics not reported	• 1.0 T MRI or 1.5 T MRI with Philips Gyroscan ACS II	Electrical parameters of the device Patient discomfort, adverse events Local changes at device site	No reports of unusual signs requiring premature termination of the MRI. No break in the lead wires on the MRI images. The clinical effects of DBS on movement disorders remained unchanged. No changes in the voltage, pulse width, DBS frequency, or impedances. Authors' conclusions: Under the same configuration of the DBS system and with careful monitoring, MRI at 1.5 T can be performed with minimal risk and no damage to the device.
Nazzaro et al., 2010[69] United States Study years: 1995 to 2007 Study funding: No outside funding	n = 249 patients (445 MRI examinations) Inclusion criteria: • All patients with DBS hardware who underwent MRI during the study period Patients: Characteristics not reported	• 1.5 T MRI with MAGNETOM Vision, Vision Plus, or SP	• Clinical or hardware-related adverse events	No clinical adverse events observed. No clear relationship between MRI scanning and implanted pulse generator malfunctions (16 cases). Authors' Conclusion: 1.5 T MRI can be safely performed on patients with DBS hardware under the conditions of the study (e.g., MRI platforms, RF coils, and scan sequences used).

Table 2: Included Studies of MRI Safety in Pediatric Patients or Patients with Implanted Devices				
Study	**Patient Population**	**Imaging Procedure**	**Safety Outcomes**	**Relevant Safety Findings**
COCHLEAR IMPLANTS				
Crane et al., 2010[70] United States Study years: 2006 to 2010 Study funding: NR	n =16 patients (22 MRI scans) Inclusion criteria: • Patients with cochlear implants undergoing MRI during the study period Patients: M/F: 7/9 Mean age: 43 ± 22	• 1.5 T MRI with Philips Achieva, Siemans Esprit or Siemans Avanto • Cochlear implant was bound prior to imaging, but magnets left in place	Harm to patient or device	No displacement of cochlear implants. One case of magnet polarity reversal of the cochlear implant. Typically, patients experienced pressure or mild pain at the device site. Authors' conclusions: MRI is safe and feasible in patients with cochlear implants.
IMPLANTED SPINAL INFUSION PUMP				
Diehn et al, 2011[71] United States Study years: 1998 to 2004 Study funding: NR	n = 86 patients (112 exams) Number of exams: M/F: 49/63 Age range: 21 to 90 years Inclusion criteria: • Patients with implanted SyncroMed EL pumps who underwent routine clinical MRI	• 1.5 T MRI was Signa or MAGNETO • Pumps were not turned off or emptied during scan	Altered pump functioning or programming Adverse events	No reports of altered pump functioning or programming. No reports of pump heating or movement attributable to MRI. Authors' conclusions: No clinically reportable adverse events or alterations to the programming of SychroMed EL drug infusion pumps with 1.5 T MRI scanning.

ACS = acute coronary syndrome; ASA = American Society of Anesthesiologists; CMR = cardiovascular magnetic resonance; DBS = deep brain stimulator; F = female;; GE = General Electric; ICD = implantable cardioverter defibrillator; M = male; MACE = major adverse cardiac events; MI = myocardial infarction; MRI = magnetic resonance imaging; NICU = neonatal intensive care unit; NR = not reported; PCI = percutaneous coronary intervention; RF = radiofrequency; ST = segment; STEMI = segment elevation myocardial infarction; T = Tesla; TIA = transient ischemic attack; VLBW = very low birth weight.

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