Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

CADTH Optimal Use Report

Pilot Project

Guidance on 1.5 Tesla Magnetic Resonance Imaging Scanners Compared with 3.0 Tesla Magnetic Resonance Imaging Scanners

May 2011

Supporting Informed Decisions

This report is prepared by the Canadian Agency for Drugs and Technologies in Health (CADTH). This report contains a comprehensive review of existing public literature, studies, materials, and other information and documentation (collectively the "source documentation") available to CADTH at the time it was prepared, and it was guided by expert input and advice throughout its preparation.

The information in this report is intended to help health care decision-makers, patients, health care professionals, health systems leaders and policy-makers make well-informed decisions and thereby improve the quality of health care services.

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1 GUIDANCE

Based on best available evidence, albeit limited, and clinical expertise, the CADTH Magnetic Resonance Imaging (MRI) Expert Advisory Panel developed the following statements to help provide guidance in the purchasing of 3.0 Tesla (T) MRI scanners or 1.5 Tesla (T) MRI scanners.

The best available evidence suggests that for most indications the 3.0 T MRI and 1.5 T MRI appear to be similar for clinical outcomes including safety.

The CADTH MRI Expert Advisory Panel developed the remainder of the guidance based on clinical and technical expertise of MRI technology.

When considering the potential clinical advantages or disadvantages of 3.0 T MRI compared with 1.5 T MRI, the Expert Advisory Panel provides the following statements:	• For advanced clinical neuroscience assessment and therapeutics — especially for neurovascular diseases, neuro-oncology, and epilepsy — the technical and clinical experience suggest benefit of the 3.0 T MRI compared with the 1.5 T MRI. • 3.0 T MRI may be preferred over 1.5 T MRI for some cardiovascular applications such as myocardial perfusion and peripheral vascular angiography. • For oncology, excluding neuro-oncology, while the visualization of small lesions is greater with a 3.0 T MRI, the clinical implications and the balance of benefits versus harms are unclear.
When considering where 3.0 T MRI technology should be applied, the Expert Advisory Panel provides the following statements:	• 3.0 T MRI should be applied where the enhanced diagnostic capacity of 3.0 T MRI will support clinical programs. • 3.0 T MRI requires greater clinical expertise and paramedical personnel support for its operation. • There may be synergies by locating a 3.0 T MRI where there is research capacity.
When considering whether a 3.0 T MRI can function as a stand-alone unit, without on-site 1.5 T MRI back-up, the Expert Advisory Panel provides the following statements:	• Any decision about placement of a 3.0 T MRI or a 1.5 T MRI should be made with consideration given to the clinical services being delivered. • While theoretically the 3.0 T MRI could operate as a stand-alone unit, current practice would suggest that it be partnered with 1.5 T MRI to better serve the full spectrum of patients.

Of Note:

- The Expert Advisory Panel recognizes the existence of comparative evidence supporting improved image quality with 3.0 T MRI over 1.5 T MRI. The Expert Advisory Panel also recognizes that there is a lack of high-quality comparative evidence linking improved image quality to improved diagnoses, patient management, and clinical outcomes.
- 3.0 T MRI may not be suitable for some patients because of inherent artifacts and because some implanted devices are not yet approved in the 3.0 T MRI environment.
- Adherence to established safety protocols should mitigate any patient safety concerns associated with 3.0 T MRI.
- As MRI is a rapidly advancing technology with long-term service delivery commitment, future decisions regarding 3.0 T MRI or 1.5 T MRI for other clinical indications may require reconsideration as further evidence and clinical experience become available.

2 BACKGROUND

Magnetic Resonance Imaging (MRI) scanners are used in many clinical applications for patients of all ages. In Canada, patients are most likely to be scanned with a 1.5 T MRI scanner; however, more powerful magnet strengths such as 3.0 T MRI are now available for clinical applications. With the stronger magnet field strengths comes the potential for increased imaging capabilities.

The decision to purchase a 1.5 T MRI scanner or a 3.0 T MRI scanner can be difficult, as MRI scanners are costly, rapidly advancing technologies that limited rigorous comparative evidence reporting on patient benefits including improved diagnoses, patient management, and clinical outcomes (that is, patient-relevant outcomes such as subsequent patient mortality or morbidity). The decision is further complicated by having to consider current and future clinical applications, and the fact that the purchased MRI may need to be used for a number of years.

Given the complexity of decisions involved in the purchase of an MRI, CADTH's MRI Expert Advisory Panel has provided guidance to help Canadian jurisdictions considering the purchase of a 1.5 T MRI or 3.0 T MRI make informed decisions. The guidance was based on the best available evidence, and clinical and technical expertise.

3 SUMMARY OF APPROACH AND EVIDENCE

3.1 Approach

In developing the guidance, the CADTH MRI Expert Advisory Panel considered the following:

- A systematic review examining evidence as to the comparative clinical effectiveness (that is, benefits and safety) and limitations of 1.5 T MRI and 3.0 T MRI scanners.
- A supplemental narrative review of published evidence on the safety of 1.5 T MRI or 3.0 T MRI for all clinical applications. This review extended the evidence base from the systematic review by summarizing primary studies, widened the patient population to healthy volunteers, and addressed safety for pediatric populations and patients with implanted devices.
- Manufacturer information.
- Clinical and technical expertise.
- Public values and preferences.

This guidance report and the systematic review with the supplemental review of safety and manufacturer information were posted for public comment on March 24, 2011.

The final guidance report and final systematic review with supplemental review of safety and manufacturer information can be found on the CADTH website <www.cadth.ca> at <www.cadth.ca/media/pdf/mri_science-report_rapid-r_e.pdf>, as of May 16, 2011.

3.2 Evidence

3.2.1 Benefit

The systematic review included 25 studies that reported on various clinical test parameters of 1.5 T MRI compared with 3.0 T MRI. None of the identified evidence assessed differences in diagnoses,

patient management, and clinical outcomes between the two technologies. All of the included studies were of low quality; that is, they were highly susceptible to bias and should be interpreted cautiously.

There was some weak evidence suggesting that there may be no differences between 3.0 T MRI and 1.5 T MRI regarding various clinical test parameters; for example, identification of brachial plexus tumours, and image quality of renal artery stenosis.

There was some weak evidence suggesting that 3.0 T MRI may be better than 1.5 T MRI for some clinical parameters such as lesions for multiple sclerosis or hepatic metastases.

There was some weak evidence suggesting that 1.5 T MRI may be better for tumour delineation of the prostate, when compared with 3.0 T MRI.

3.2.2 Harm and Limitations

The supplemental review identified 18 studies (1.5 T MRI and/or 3.0 T MRI); all supported the safety of both field strengths in pediatric populations, as well as patients with implanted devices. All of the included studies were of low quality. Most of the studies focused on 1.5 T MRI.

For 1.5 T MRI and 3.0 T MRI scanners, no evidence on safety was found for geriatric populations, healthy adults, or adults without implanted devices.

3.2.3 Cost and Cost-Effectiveness

An economic evaluation was not conducted because of the lack of comparative clinical data, wide within- and between-health setting variation in the costs of the MRI technology (hardware and software), the range of costs in MRI technology across clinical applications, and the difficulty in determining how costs would increase or decrease (for example, costs of using less or more contrast agent) with the technology.

3.2.4 Additional Context and Discussion Points from the MRI Expert Advisory Panel

The Expert Advisory Panel acknowledges that 3.0 T MRI, in general, provides better quality images, largely due to increased signal-to-noise ratios, in patients who do not have inherent artifact issues.

There is a lack of evidence linking higher-quality images produced by the 3.0 T MRI (compared with 1.5 T MRI) with better patient diagnoses, patient management, and clinical outcomes.

While 1.5 T MRI is a good technology for some indications, the preference would be to use a 3.0 T MRI in advanced neurological applications.

While there is a lack of studies assessing how 3.0 T MRI benefits patient diagnoses, patient management, and clinical outcomes, the Expert Advisory Panel indicated that local availability of a 3.0 T MRI may improve patient care in selected cases by reducing the need for multiple diagnostic tests, and reducing patient travel to access 3.0 T MRI located at a more distant site or outside the province of residence.

Increased clinical applications in the short- and long-term may be possible with access to 3.0 T MRI scanners. Safety precautions with the 3.0 T MRI are similar to the precautions for 1.5 T MRI (for example, noise, certain devices that are not compatible or have not been tested in the 3.0 T MRI,

sedation in children), but the adherence to established safety protocols should mitigate the risk of harm.

Purchase and installation factors that have large cost implications are different for each location and would be defined within a specific Request for Proposal process.

To enhance efficiency of care, placement of a 3.0 T MRI should occur in health care settings capable of providing clinical management of the patient who requires a 3.0 T MRI scan.

The faster scan time of a 3.0 T MRI does not necessarily result in more patients scanned per day, as the protocols and procedures are not shorter than 1.5 T MRI. Some health care settings may be able to gain a quarter of an hour, whereas other health care settings will not gain time.

3.2.5 MRI Expert Advisory Panel

The MRI Expert Advisory Panel (Table 1) was comprised of a public member, members with expertise in the critical evaluation of evidence, and members with expertise in radiology. All of the Expert Advisory Panel members were involved in the guidance development. The biographies and conflicts of interest can be found on the CADTH website <www.cadth.ca>.

Table 1: MRI Expert Advisory Committee Members

Dr. Jean Gray, Chair	Dr. Scott Klarenbach
Dr. Martin Charron	Dr. Andre le Roux
Mr. Harlon Davey (public member)	Dr. Lindsay Nicolle
Dr. Alexander Dick	Dr. Matthias Schmidt
Dr. Darren Ferguson	Dr. James Silvius

MRI = magnetic resonance imaging.