TITLE: Magnetic Resonance Imaging for Patients with Valvular Heart Disease: A Review of Clinical-Effectiveness

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CONTEXT AND POLICY ISSUES:

Imaging evaluation of the heart encompasses structural evaluation of the chambers, valves and coronary arteries, and functional evaluation, which includes assessment of perfusion, wall motion, and myocardial viability. Various imaging modalities are used to assist in the diagnosis and evaluation of abnormalities of the heart. Echocardiography and x-ray-based angiography are considered gold standard tests for most of the abnormalities. Doppler-echocardiography is the most frequently used tool due to its noninvasiveness, cost-effectiveness, wide availability, and capability to provide sufficient information for clinical patient management yet poor acoustic windows and heavy calcification of the valves can jeopardize the quality of images. Angiography via cardiac catheterization may not be an optimal imaging technique as it is invasive, exposes patients to radiation and iodinated contrast media (which carries a non-negligible risk of life-threatening complications), and is questionable in its ability to precisely quantify valvular regurgitation.

Magnetic resonance imaging (MRI) is well established for the structural and functional evaluation of the heart. It has several unique advantages relative to the other diagnostic modalities. Compared to echocardiography, MRI is not limited by acoustic windows, which gives the operator a great variety of achievable views; MRI can also be used to examine flow in any direction, not limited to toward or away from the transducer, and can be tuned to any velocity range without aliasing. Compared to catheterization, MRI is not invasive, and does not expose patients to radiation and iodinated contrast media that limits catheterization’s applicability in daily routine.

This HTIS report examines the evidence on clinical effectiveness of MRI in evaluating valvular heart disease compared to the echocardiography and angiography, the current gold standards.
RESEARCH QUESTION:

What is the clinical-effectiveness of magnetic resonance imaging for the evaluation of patients with valvular heart disease?

METHODS:

A limited literature search was conducted on key health technology assessment (HTA) resources, including OVID Medline, Embase, The Cochrane Library (Issue 1, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. Results include articles published between 2004 and March 2009, and are limited to English language publications only. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and controlled clinical trials.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, HTAs, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and controlled clinical trials.

SUMMARY OF FINDINGS:

From this limited literature search, we identified one HTA and three non-randomized controlled studies assessing the clinical effectiveness of MRI in evaluating valvular heart disease. We did not identify any relevant systematic reviews, meta-analyses, or randomized controlled trials about MRI for the target population.

Health technology assessments

A Belgian HTA report systematically evaluated the evidence of the clinical effectiveness of MRI in a variety of clinical disorders, including valvular heart disease. The literature search time frame was from January 2000 to January 2006. Two relevant primary studies were in the HTA report, one with 44 symptomatic patients with severe aortic stenosis and the other with 22 patients with mitral stenosis. MRI showed comparable diagnostic accuracy when compared to catheterization (sensitivity, 78% to 89%; specificity, 75% to 89%) and when compared to transesophageal echocardiography or transthoracic echocardiography (TEE or TTE) (sensitivity, 70% to 74%; specificity, 67% to 70%). MRI also had good correlation with catheterization ($r=0.89, p<0.0001$), and with TEE or TTE ($r=0.89, p<0.0001$). There were no details provided regarding the quality of these two trials. The authors stated that there was growing evidence that MRI may become important in assessing patients with valvular stenosis.

Systematic reviews and meta-analyses

No systematic reviews or meta-analyses were identified.

Randomized controlled trials

No randomized controlled trials were identified.

Controlled clinical trials

Three non-randomized controlled trials were retrieved. All MRI exams were performed using a 1.5-Tesla magnetic resonance system. The summaries are presented below; however, more details of the trials and the main findings are presented in Appendix 1, Table 1.
Pouleur et al. compared the accuracy of aortic valve area (AVA) measurements obtained from MRI and TEE in 48 patients with aortic valve disease. All patients were scheduled to undergo cardiac surgery. TTE was used as the reference (gold) standard. Measurements were performed independently by two observers blinded to patient-identifying information. MRI and TTE were performed on the same day. The main finding was that the mean image quality grades with MRI were 3.7 out of 4.0 in a four-point ordinal Likert scale. This indicated that planimetry of the AVA was successfully performed. MRI-derived AVA highly correlated with TTE-derived AVA values ($r = 0.96$, $p < 0.001$) even though there was significant difference between them with regard to AVA values (difference: $-0.4\pm0.5$ cm$^2$, $p<0.001$). The sensitivity and specificity of MRI for the detection of moderate (AVA $<1.2$ cm$^2$) and severe (AVA $<0.8$ cm$^2$) aortic stenoses were high. Based on the results, the authors concluded that MRI can be used to measure the AVA and detect aortic stenosis.

Haghi et al. compared the AVA measurements by MRI with right heart catheterization and Doppler echocardiography in 20 patients with moderate or severe aortic stenosis. There were no significant differences between MRI-derived AVA and catheterization-derived AVA, or between MRI-derived AVA and echocardiography-derived AVA. MRI and catheterization classified all patients into the same severity category of aortic stenosis. One patient was classified differently by MRI and echocardiography. In this patient, AVA was $1.18$ cm$^2$ when measured by echocardiography and $0.89$ cm$^2$ when measured by MRI. The authors concluded that the MRI can replace catheterization in determining AVA in aortic stenosis. In addition, the authors indicated that because MRI is more time-consuming and more costly than Doppler echocardiography, it will not replace the latter in everyday clinical routine. However, the authors stated that MRI could be a valuable adjunct in the diagnostic work-up of the patients when: 1) AVA measurements cannot be reliably performed by echocardiography; or 2) there are conflicting results of various tests and further clarification by an alternative method is required.

Debl et al. compared planimetry of AVA by MRI with TEE and catheterization in patients with suspected or known aortic stenosis. MRI and catheterization were performed in all 33 patients, while TEE was performed in 27. All three exams were conducted within one week. Planimetry of AVA by MRI produced images with better quality as compared to TEE. MRI slightly overestimated AVA as compared to catheterization (mean difference $0.20\pm0.17$ cm$^2$, $p < 0.0001$), despite an excellent correlation ($r = 0.80$, $p < 0.0001$). The authors reported a significant difference between MRI-derived AVA and TEE-derived AVA (MRI-derived: $0.94\pm0.29$ cm$^2$; TEE-derived: $0.85\pm0.31$ cm$^2$, $p < 0.001$), but they correlated well with each other ($r = 0.86$, $p < 0.0001$). The authors concluded that MRI provided good quality images which allowed for comparable visualization and planimetry of AVA in patients with valvular aortic stenosis. AVA planimetry by MRI correlated well with AVA planimetry by catheterization. A good correlation to AVA planimetry by TEE was also observed, but image quality was better in MRI than in TEE. Therefore, the authors stated that severe aortic stenosis can be detected by MRI with high sensitivity and specificity. However, a slight overestimation of AVA by MRI has to be taken into account in the clinical management of these patients.

Limitations

- There were no systematic reviews or randomized controlled trials evaluating the performance of MRI in the target population identified from 2004 to date.
- There were a limited number of HTA reports and non-randomized controlled trials available.
- Quality of the studies was questionable.
bias might have been introduced since the diagnostic exams being compared were performed at different times
• it was unclear whether investigators were blinded to patients’ characteristics, which may have introduced bias
• the included studies might not have had sufficient power to detect meaningful differences between comparison groups because of small sample sizes

- Only AVA measurements and diagnostic accuracy were examined in the selected studies; more clinically relevant outcome measures were missing such as the effect of MRI on clinical management and patient’s prognosis.
- The studies focused on patients with aortic stenosis; therefore, we could not evaluate the use of MRI for other valvular heart diseases. In addition, different training programs and the different experience of the professionals who performed and interpreted the exams (for example, MRI, TEE/TTE, and catheterization) may have affected the results; however these variables were not reported in the included studies and therefore the potential affect remains unknown.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

The assessment of cardiac function, valvular morphology, and quantification of valvular stenosis and regurgitation are the most important imaging tasks in valvular heart disease.\textsuperscript{5} Yet, published evidence for answering the research question is very limited. One HTA report assessed the use of MRI in patients with various heart diseases, including aortic stenosis and mitral stenosis; while majority of the patients enrolled in the three non-randomized trials had aortic stenosis. Thus, we were not able to evaluate MRI in patients with other valvular diseases, such as mitral regurgitation.

According to the available evidence, MRI can produce images with better quality as compared to echocardiography. Image quality was not compared between MRI and catheterization. AVA measurements derived by MRI correlated well with the current gold standards, echocardiography and angiography. However, there was a trend for MRI to slightly overestimate the value of AVA, which needs to be taken into account along with other clinical considerations.

Thus, there is evidence that MRI may be an option in evaluating patients with aortic stenosis given its advantages such as non-invasiveness, ability to provide good quality images, and high diagnostic accuracy.

However, additional, well-designed clinical studies are required in order to provide more rigorous evidence on the clinical effectiveness of MRI in evaluating aortic stenosis as well as other valvular heart diseases.

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REFERENCES


## APPENDIX 1

### Table 1. Design Details and Main Findings from the Controlled Trials Examining Clinical Effectiveness of MRI Exams on Valvular Heart Disease

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
<th>Intervention and comparison</th>
<th>Results</th>
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| Pouleur et al.,   | 48 pts (27 had aortic stenosis, 21 had aortic or mitral regurgitation)  | MRI versus CT vs. TEE versus 2-Dimensional Doppler TTE | AVA (mean±SD, cm$^2$)  
MR-derived: 2.4±1.8  
TTE-derived: 2.0±1.5, $r = 0.96$, p<0.001  
Diagnostic accuracy of MR (reference TTE)  
Sensitivity for moderate aortic stenoses: 95%  
Specificity for moderate aortic stenoses: 97%  
Sensitivity for severe aortic stenoses: 91%  
Specificity for severe aortic stenoses: 95% |
| 2007$^7$          |                                                                          |                                               |                                                                         |
| Haghi et al.,     | 20 pts with moderate or severe aortic valve stenosis                     | MRI versus CATH versus echocardiography       | AVA (mean±SD, cm$^2$)  
MRI-derived: 0.84±0.21  
CATH-derived: 0.82±0.23 (no significant difference vs. MRI, p value not reported)  
Echocardiography: 0.88±0.25, p=0.89 vs. MRI |
| 2006$^4$          |                                                                          |                                               |                                                                         |
| Debl et al.,      | 33 pts with known or suspected valvular aortic stenosis                  | MRI versus CATH versus TEE                    | % of pt with adequate image quality  
MRI: 27/33, 82%  
TEE: 15/27, 56%, p=0.05  
AVA (mean±SD, cm$^2$)  
MRI-derived: 0.94±0.29  
TEE-derived: 0.85±0.31, p=0.05 vs. MRI  
CATH-derived: 0.74±0.24, p <0.0001 vs. MRI  
Correlation  
MRI-AVA and CATH-AVA: 0.80, p <0.0001  
MRI-AVA and TEE-AVA: 0.86, p <0.0001 |
| 2005$^8$          |                                                                          |                                               |                                                                         |

AVA = aortic valve area; CATH = catheterization; CT = computed tomography; MRI = magnetic resonance imaging; pt = patient; SD = standard deviation; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography