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AN INITIATIVE OF THE NATIONAL, STATE AND
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AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Low-field 0.2-0.5 tesla MRI for the detection of arthritis

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PRIORITISING SUMMARY

REGISTER ID: 000371

NAME OF TECHNOLOGY: LOW FIELD 0.2-0.5 TESLA MRI

PURPOSE AND TARGET GROUP: FOR THE DETECTION OF ARTHRITIS AND MUSCULOSKELETAL DISEASE

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|--|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input checked="" type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|---------------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 92846, 147022 |
| <input type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

Two units have TGA approval and are described as MRI systems for extremity imaging with a permanent magnet. One is sponsored by Medtronic Australia Pty Ltd (ARTG 92846), however it appears that Medtronic currently do not distribute this scanner in Australia. The other unit, the ESAOTE-G scanner is distributed by Biolab Australia Pty Ltd (ARTG 147022).

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Denmark	✓		
United States	✓		

IMPACT SUMMARY:

Several units of low-field magnetic resonance imaging (MRI) are manufactured for the purpose of identifying individuals with early symptoms of bone and joint disease. The technology would be made available through general practitioners, outpatient clinics and hospitals.

BACKGROUND

MRI scanners are ideal for imaging soft tissues in the body as they use a pulsed oscillating magnetic field to affect the magnetic behaviour of hydrogen nuclei in the

body. Not only is MRI sensitive to differing signals from one tissue compared to another, but is sensitive to changes in the hydrogen concentration within tissues and fluids. When tissue is placed in a magnetic field and a radio-frequency is applied, the alignment of the hydrogen nuclei changes so that they are oscillating perpendicular to the main field direction (excitation). Once the pulse is removed, the realignment, or relaxation, of the nuclei is slower due to the effect of the constant magnetic field exerted by the MRI scanner. The relaxation time is referred to as T1. Hydrogen nuclei in blood and cerebrospinal fluid have a long relaxation time, compared to nuclei in tissues, with hydrogen nuclei in fat cells having the shortest relaxation time of approximately 300 milliseconds. The differences in realignment and spin times appear as differences in brightness on the MR image (FASEB 2007).

The rate of relaxation will depend on the strength of the constant magnetic field (FASEB 2007). Magnetic field strength is expressed units of Tesla (T). The strength of magnets may vary: ultra-high field (4.0 to 7.0 T, mostly used for research); high field (1.5 to 3.0 T); mid field (0.5 to 1.4 T); low-field (0.2 to 0.4 T); and ultra-low field (less than 0.2T). In addition, there are three main types of magnet design: permanent magnets which are suited to open scanners (0.2 T) and can not be turned off; resistive magnets, which use an electric current running through a coil to produce a magnetic field; and superconducting magnets. The majority of MRI scanners use superconducting magnets, which operate such at low temperature that resistance is negligible, allowing strong electric currents, and hence high magnetic fields, to be generated without generating heat (Hashemi et al 2004).

MRI has been proposed as a suitable method for the early detection and diagnosis of joint diseases, including rheumatoid arthritis. Low-field MRI scanners (0.2 T) are considered to be ideal for assessing the extremities such as hands and peripheral joints. Low-field MRI scanners are open and are therefore considered to be more comfortable for patients, especially those who may be claustrophobic, compared to high field scanners. In addition, the purchase price of low-field MRI scanners is lower compared to conventional scanners (Lindegaard et al 2006).

CLINICAL NEED AND BURDEN OF DISEASE

Reliable incidence and prevalence data for arthritis and musculoskeletal conditions are lacking in both Australia and New Zealand. Prevalence data in particular are generally ascertained from health surveys, which rely on self reported data and are therefore estimations of the true prevalence of disease. Arthritis and musculoskeletal conditions are one of the most common reported chronic conditions in Australia and New Zealand.

In the 2001 Australian National Health Survey 32.3 per cent of respondents reported arthritis or a musculoskeletal condition lasting longer than six months. This number equates to approximately six million Australians experiencing chronic illness or pain from arthritis, back pain, osteoporosis, osteoporotic fractures as well as

musculoskeletal and connective tissue diseases. Approximately 13.3 and 1.3 per cent of the total population reported having arthritis and rheumatism, respectively, in 2001 (AIHW 2005).

In 2005, Access Economics reported on the prevalence of arthritis conditions in New Zealand. Data were obtained from the Ministry of Health’s New Zealand Health Survey (NZHS), which summarises *self-reported* prevalence data. In addition, prevalence data from a primary care survey were included (Table 1). Raw prevalence data for all types of arthritis are shown in Figure 1 (Access Economics Pty Ltd 2005).

Table 1 Prevalence rates of arthritis in New Zealand

	Osteo-arthritis (%)	Rheumatoid arthritis (%)	All forms arthritis (%)	All forms musculoskeletal disorder (%)
NZHS community based study, 2003	7.7	3.2	15.7	32.7
Taylor et al (2004) primary care based study, 2003	1.44	0.79	3.75	20.4
Colmar Brunton community based study, 2003	n/a	n/a	n/a	24.6

(Access Economics Pty Ltd 2005)

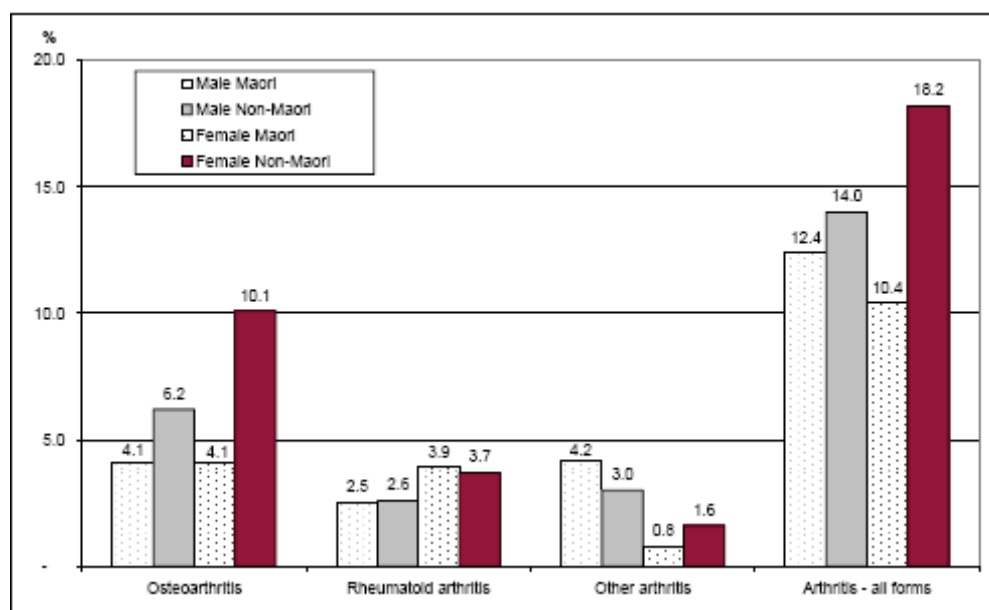


Figure 1 Raw prevalence rates by type of arthritis, New Zealand 2003 (Access Economics Pty Ltd 2005)

Arthritis is associated with increasing age, therefore with the ageing of the population it may be expected that the prevalence of this condition may increase.

DIFFUSION

Biolab Australia Pty Ltd currently distributes the ESAOTE-G 0.27 tesla MRI scanner in Australia. There are at least three units operating in Australia (Albury, Newcastle and St George Private Hospital, Sydney, NSW). These units are currently used for a

mixed clientele of physiotherapy, chiropractic, orthopaedic and general practice patients (personal communication Biolab Australia Pty Ltd).

COMPARATORS

Rheumatoid arthritis is diagnosed using a combination of clinical observation and laboratory testing. The disease is difficult to diagnose in its early stages and symptoms can vary enormously between patients and may overlap with symptoms of other forms of arthritis and joint disease. The American College of Rheumatology developed a set of criteria for the diagnosis of RA, where four out of seven signs and symptoms are required for a firm diagnosis (Table 2).

Table 2 American College of Rheumatology rheumatoid arthritis diagnostic criteria

Criteria	Comment
1 Morning stiffness	Duration > 1 hour; lasting > 6 weeks
2 Arthritis of at least 3 areas	Soft tissue swelling or exudation lasting > 6 weeks
3 Arthritis of hand joints	Wrist, metacarpophalangeal joints or proximal interphalangeal joints lasting > 6 weeks
4 Symmetrical arthritis	At least one area, lasting > 6 weeks
5 Rheumatoid nodules	As observed by a physician
6 Serum rheumatoid factor	As assessed by a method positive in less than 5% of control subjects
7 Radiographic changes	As seen on anteroposterior films of wrists and hands

Source: (AIHW 2005)

SAFETY AND EFFECTIVENESS ISSUES

Three studies, which were conducted on patients with rheumatoid arthritis (RA) of the hand, fingers or wrist, were identified for inclusion in this Prioritising Summary. A clinical trial, where patients (n=130) diagnosed with early symptoms of RA were randomised to a treatment regime, then disease progression was monitored with X-ray and 0.2 and 1.0 T MRI at baseline, 6 and 12-months, was excluded as the MRI results were not differentiated from each other (Hetland et al 2008). One study used 0.2 T to assess patients suspected of cervical spondylotic myelopathy, however no comparative scanning modality was used (Hori et al 2006). In addition, low-field MRI (0.2 T) has been used to scan women at high risk of breast cancer and to guide corticosteroid injections into the sacroiliac joints of patients with spondylarthropathy (Gunaydin et al 2006).

The diagnostic capabilities of low-field MRI (0.2 T), high field MRI (1.0 T) and conventional X-ray were compared in 37 patients clinically confirmed to have RA¹ and 28 controls (Ejbjerg et al 2005). The same radiologist or clinician performed all evaluations, which were blinded to the results of the evaluations by other modalities. High field MRI was considered to be the reference standard. Images were assessed for the presence of bone erosion, synovitis and bone marrow oedema. The sensitivity, specificity and accuracy of low-field MRI for bone erosion were 94, 93 and 94 per

¹ Median disease duration 5 years, range 1-37 years

cent, respectively, compared to the corresponding values of 33, 98 and 83 per cent for conventional X-ray. The sensitivity, specificity and accuracy of low-field MRI were high when used to diagnose synovitis at 90, 96, and 94 per cent. However the sensitivity was poor when low-field MRI was used to diagnose bone marrow oedema (39%) with high specificity (99%) and accuracy (95%). The significance of this finding is unclear as the position of bone marrow oedema in the progression of RA disease has not been resolved. If the presence of bone marrow oedema is an interim phase between the presence of synovitis and bone erosion, then the low sensitivity of low-field MRI may have little impact. The intraclass correlation coefficients between low and high-field MRI scores were 0.923 ($p<0.05$) for synovitis and 0.936 ($p<0.005$) for bone erosions (level II diagnostic evidence).

A small-scale study, conducted on 24 consecutive patients with clinically confirmed RA of less than 12-months duration monitored patients at baseline and after 6 and 12 months of methotrexate treatment (Lindegaard et al 2006). Patients were monitored with clinical and biochemical examinations, 0.2 T MRI and X-ray. MRI assessors were blinded to the clinical and radiographic findings. Images were assessed for the presence of bone erosion, synovitis, tenosynovitis² and bone marrow oedema. At the end of 12-months treatment both the erythrocyte sedimentation rate and C reactive protein levels in all patients were significantly reduced ($p=0.002$). At baseline, X-ray detected 15 bone erosions in six patients, compared to the 21 bone erosions detected by MRI in 10 patients. One erosion, detected by X-ray, was not detected by MRI, however only six (29%) of the MRI erosions were detected by X-ray. At 12-months, X-ray detected 17 bone erosions in seven patients, of which eight were new erosions and six detected at baseline were no longer visible. X-ray progression of disease therefore occurred in five patients. MRI detected 15 new erosions in eight patients at 12-months follow-up and only one of the baseline erosions was no longer visible. Four (19%) of the bone erosions visible on MRI progressed to being visible by X-ray at 12-months. The median MRI synovitis score at baseline was eight (range 4-11), which was reduced significantly at 12-months to four (range 0-7) ($p<0.001$). Baseline scores for bone oedema and tenosynovitis were zero (range 0-1.5 and 0-0.25, respectively). These values remained unchanged over the course of the 12-month treatment. However, joints with mild synovitis MRI detected at baseline had a relative risk of 7.3 of having bone erosions detected by MRI at 12-months compared to joints which were synovitis free at baseline. For joints with severe synovitis at baseline, this relative risk increased to 10.7. The number of new bone erosions detected by MRI at 12-months correlated significantly with the baseline synovitis score ($r=0.61$, $p<0.001$). From these results it appears that low-field MRI is effective in the preliminary diagnostic investigation of patients with *early* symptoms of RA (level II diagnostic evidence).

² Tenosynovitis = inflammation of a tendon sheath

A similar study compared the use of high (1.0 T) and low-field (0.2 T) MRI and conventional radiography to monitor 18 consecutive patients³ with confirmed RA who were undergoing therapy. Results from all screening modalities were assessed independently by two reviewers (Taouli et al 2004). No significant difference was reported in the ability of high or low-field MRI to detect bone erosions (27.5 ± 9.8 and 28.8 ± 10.0 , respectively) ($p=0.71$). However, both high and low-field MRI detected significantly higher numbers of bone erosions compared to X-ray (13.1 ± 8.3) ($p<0.001$). Similarly there was no statistically significant difference between the joint-space narrowing scores obtained with high and low-field MRI (15.2 ± 8.3 and 14.5 ± 10.4 , respectively). Although these scores were slightly higher than those obtained with X-ray (12.7 ± 9.6) there was no statistically significant difference ($p=0.70$). In addition, scores obtained with all modalities had high standard deviations indicating a great deal of variation in the small patient group. There was no difference in synovitis scores obtained with high and low-field MRI ($p=0.14$). The inter-observer agreement for MRI scores was good to excellent with correlations of 0.83 to 0.94 (level III-2 diagnostic evidence).

COST IMPACT

A complete ESAOTE-G 0.27 tesla MRI scanner (scanner, cage plus software) currently costs \$875,000 plus GST. This price does not include the cost of a laser printer for films which may cost up to \$15,000. As these scanners use a permanent magnet they do not require expensive cryogenic capabilities and have low daily running costs (2 kW versus 1000 kW for conventional MRI scanners). The patient must bear the full cost of a scan with a low-field MRI scanner as the Medicare Benefits Schedule currently reimburses only scans performed on scanners that are greater than, or equal to, 1.5 tesla (personal communication Biolab Australia Pty Ltd).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

In July 2004, a Prioritising Summary was written on the use of the PoleStar intra-operative (low field) MRI for head and neck surgery. This summary was referred on the basis that Queensland Health was writing a Health Technology Assessment on all forms of intra-operative MRI. PoleStar is now distributed by Medtronic, and although 40 units are now in use world wide, there are currently no units in use in Australia.

SUMMARY OF FINDINGS

Only one, good quality, study reported on the comparison of screening modalities for patients with early symptoms of RA. Two other studies were included which monitored patients with long-term disease. In all three studies it was reported that

³ Mean disease duration 8 years, range 1-11 years

low-field MRI performed as well as high-field MRI and X-ray in the detection of bone erosions. In addition, low-field MRI was effective in detecting synovitis. Low-field MRI is cheaper to perform than high-field MRI.

HEALTHPACT ACTION:

Based on the good quality evidence it would appear that low-field MRI is useful to diagnose and monitor patients with rheumatoid arthritis. Patients are not exposed to ionising radiation and can therefore be monitored closely for the effectiveness of treatment regimes. The use of low-field MRI would appear to be increasing in Australia, raising issues surrounding MBS rebates as MRI services currently attract a rebate only when conducted in accredited centres when patients are referred by a specialist. Due to access and funding issues surrounding this technology, HealthPACT recommended that it be monitored for further information in 12-months time.

NUMBER OF INCLUDED STUDIES

Total number of studies

Level II diagnostic evidence 2

Level III-2 diagnostic evidence 1

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SEARCH CRITERIA TO BE USED:

Arthritis, Rheumatoid/complications/*diagnosis

Magnetic Resonance Imaging

Bone Diseases/diagnosis

Disease Progression

Synovitis/*diagnosis

Edema/diagnosis

Tenosynovitis/diagnosis