Magnetic resonance imaging services

A report by the

National Health Technology Advisory Panel

May 1990

Australian Institute of Health

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Any comments or information relevant to the subject matter of this report would be welcome. Correspondence should be directed to:

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May 1990

ISBN 0 642 15429 5

Published for the Australian Institute of Health by the Australian Government Publishing Service, Canberra 1990

Printed in Australia by Better Printing Service, 1 Foster Street, Queanbeyan N.S.W. 2620

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Executive summary

- Magnetic resonance imaging (MRI) is now established as a useful diagnostic technology in many examinations of the head and spine.
- Hard evidence of the cost–effectiveness of MRI in informing clinical decision making remains limited. The technology has promise in many areas, but further work is needed to establish its relative advantage over other diagnostic technologies.
- A variety of MRI scanners are available, differing in the type and field strength of the magnet used. The Panel considers that there is no optimum type of scanner and that decisions on procurement should be made on a case by case basis. The Panel considers that at present:
  - mid–field superconductive systems appear to offer advantages in terms of capital and operating costs and to give good image quality
  - high–field systems can provide high quality diagnostic services, but their superiority over mid field systems is not established in terms of influence on clinical decision making
  - lower field systems, some based on permanent magnets, offer the potential for reducing costs of MRI, but further information on their technical capability and clinical effectiveness is needed.
- The Panel does not support the acquisition of MRI scanners with field strengths of greater than 1.5T, except in the context of medical research.
- The performance of MRI is enhanced in some examinations by the use of contrast agents such as gadolinium–DTPA. The Panel supports the more general availability of such materials in Australia, but notes that criteria for their use will need to be developed and that they may increase the cost of MRI services.
- The safety of MRI appears to be acceptable, if appropriate safeguards are taken to avoid exposure of ferromagnetic objects to the magnetic field of the scanner.
- The costs of MRI examinations may decrease in future with the availability of cheaper magnets and faster scanning sequences. However, MRI can be expected to remain an expensive diagnostic imaging technology with higher costs than CT scanning.
- It is necessary for units operating MRI scanners to acquire appropriate hardware and software updates to maintain acceptable standards of performance.
- The Panel considers that expansion of MRI facilities in Australia should be cautious, and concentrated where the comparative advantage of the technology is best established.

Recommendations

The Panel recommends that:

- Priority is given to providing access to MRI for hospitals with substantial neurosurgical responsibilities. This would imply a total of about 16 MRI units nationally in neurological teaching hospitals.
- Those private sector units which are currently associated with public hospitals are brought into any national review of MRI facilities.
- MRI is used by specialised personnel in the most cost–effective way. This implies some restriction on access to the technology to ensure its efficient usage.
- The costs of upgrades to hardware and software are included in all operating budgets.
- The development and use of MRI be kept under review, particularly in newer areas of application such as cardiovascular imaging.
- All public sector MRI units be required to routinely collect information on the examinations they undertake so that a data base can be developed on the evolving role of the technology. Similar routine data collection at private MRI facilities should be encouraged.

Introduction

In 1983 the National Health Technology Advisory Panel issued a report on NMR Imaging(1) which gave a brief description of what was then an emerging diagnostic imaging technology and made suggestions concerning its introduction into Australia. A major recommendation of the report was that there should be a controlled introduction of NMR imaging scanners and that the use of these should be assessed in a public hospital setting prior to support for any wider diffusion of the technology. This recommendation led to the establishment of the MRI assessment program in five public hospitals. The basis of the assessment was outlined in the Panel's 1984 report on Selection of Sites(2) and data have been presented in a series of publications(3,4).

Since the initial report, there have been a number of developments in magnetic resonance imaging (MRI), as the technology is now usually called, including the acquisition of Australian primary data. The NHTAP considered that it was, therefore, now opportune to undertake a further appraisal of this imaging method.

The present report reviews developments in MRI and experience gained in its routine clinical use, including that in the Australian situation. The report is not concerned to any extent with the use of NMR spectroscopy in medicine in Australia, or overseas use of spectroscopy with whole body machines.

Basic technical details

Commercial MRI scanners make use of a large magnet which surrounds the patient and produces a homogeneous field. Subsidiary coils are used to modify the field and to transmit and receive radiofrequency (RF) signals. The scanning sequence, tomographic image reconstruction and presentation are handled by a computer. Construction of an image makes use of detection and computer manipulation of RF signals from atomic nuclei in the part of the body under investigation. Such signals are generated by changes in the magnetic and RF fields applied to the body. There is considerable variation possible in the RF pulse sequences used in MRI scans, giving scope for manipulating the characteristics of the image produced.

The magnet in an MRI scanner may be superconductive, resistive or permanent. Superconductive magnets require liquid helium to enable them to operate. Magnetic field strength is commonly specified in terms of the Tesla (T) which is equivalent to 10 kilogauss. In descriptions of MRI, field strengths of more than than 1.0T have been considered as high, medium field strength being down to about 0.3T, with low field strengths below that figure. High field strength operation is possible only with superconductive machines.

Care is required in siting MRI scanners to ensure that account is taken of the stray magnetic fields from the instruments and the need to screen the scanner from RF fields in the environment.

Diffusion of the technology

At the time of preparation of the Panel's first report in 1983, opinion from US sources and in some of the submissions received by NHTAP was that MRI would probably supersede CT scanning for most indications over the next decade. However, the Panel considered the replacement of CT units over the five years from 1983 was unlikely to be significant and the opinion of the Panel's Technical Committee was that MRI would be unlikely in the foreseeable future to provide the wide dramatic advance in diagnostic capability that occurred with the introduction of CT scanning(2). The Panel has more recently confirmed its impression of the continued dominant role of CT scanning in a separate report on that technology(5).

Diffusion of MRI scanners has been considered by several authors(6–8). It has been noted that although MRI scanners have continued to diffuse rapidly, particularly in the USA and Japan, the rate of diffusion is significantly less than that of CT at a comparable stage of technological development. Steinberg et al have noted that factors contributing to this slower rate of diffusion include changes to the technical capability of the machines, availability of effective diagnostic imaging technologies (particularly CT), the high cost of MRI scanners, relatively recent investment by radiology practices in CT equipment and regulatory control by government(6).

As at October 1989 there were about 1300 MRI scanners in the USA and 4000 CT scanners. Steinberg has noted that MRI scanners are diffusing much more rapidly in the USA than in the rest of the world and that superconductive magnets have emerged as the dominant MRI technology in that country. There is also a greater tendency to install MRI scanners in out–patient settings compared with CT, in part due to DRG legislation. Diffusion within the USA has been assisted by provision of coverage by Medicare and other third party payers.

Outside the USA the two countries with widest diffusion of the technology are Japan (473 units as of May 1989) and West Germany, both of which have significant manufacturing industry involvement in production of MRI. By comparison, Canada in 1988 had only 12 MRI units. Rublee has noted that the differences between Canada, Germany and the USA in access to MRI, and some other technologies, reflect only the capacity for treatment and, in themselves, indicate little about the overall effectiveness, achievements and weaknesses of the health care systems of any of the three countries studied(9).

Use of resistive and permanent magnet MRI machines may be more popular outside the USA as space considerations and availability of liquid helium can pose problems in many countries. A significant proportion of MRI units continue to be used or associated with medical research rather than providing routine clinical services.

In Australia the five units which participated in the NHTAP assessment program included three superconductive and two resistive magnet machines. Governments have agreed to establish three further public hospital MRI units (one in Sydney, two in Melbourne). A further three superconductive machines are in operation in private practice in Sydney (1.5T and two 0.5T) and two superconductive machines (0.5T) commenced operation in Adelaide in 1990.

Magnet type and field strength considerations

At the time of preparation of the Panel's first report there was considerable debate on the relative merits of different types of magnet (superconductive/resistive) and on optimum magnetic field strength. There were a number of claims that use of higher field strength at 1.5T permitted increased patient throughput and improved image quality, in addition to giving the potential for use of scanners for spectroscopy. The Panel's Technical Committee noted in 1984 that it was not convinced of the superiority of 1.5T magnet systems and that use of any NMR spectroscopy in routine clinical applications appeared some years away and might in any case require magnets of even higher field strength(2).

The debate on the relative merits of different types of magnets and field strengths has continued. Superconductive systems have become the most popular in the USA, but resistive magnets have continued to be marketed and there has recently been an upsurge in interest in permanent magnet systems operating at lower field strength (0.2T).

Comparison of different types of machine remains difficult and there has been very little independent assessment of one type of machine against another.

The earlier work published by Evens, Jost & Evens(10) and Di Monda(11) drew attention to the additional cost of high field systems and noted that the claimed higher throughputs with these machines had not been achieved. The experience of the Australian assessment program has been that the throughput of resistive and superconductive machines was similar, although recent reports from USA indicate that high throughputs are being achieved on high field superconductive machines for some applications following recent software upgrades.

Image quality has continued to improve on instruments of all types. Comparison of high, medium and low field machines is difficult, often essentially implying a comparison between different types of software at various stages of development rather than hardware. A further complication is the lack of standardisation between different machines on specification of image. There appears to be a continued perception that higher field strength machines have advantages in imaging of the head, whereas lower field instruments produce better results in abdominal examinations. The relationship between image quality and subsequent clinical decision making continues to be complex and poorly assessed.

The Panel notes that while some of the claims for the high field systems have not been realised, several such machines have been backed by substantial research and development and provide very effective imaging systems. The Panel believes, however, that similar image quality and patient throughput may be provided by mid–field scanners operating at around 0.5T which may offer advantages through lower capital, siting and operating costs.

It is considered by some radiologists that there are observable differences, both subjective and objective between the quality of high field and mid field (0.5T) images due to the higher signal to noise ratio and the thinner slices which are achievable with higher magnetic field systems. The argument is made, usually by tertiary referral hospitals, that there is a need for definitive answers in difficult diagnostic cases and that such results are provided by the high field system. The advantage of the definitive answer, it is stated, is that it allows the cessation of the cycle of tests and diagnoses. By analogy, it is argued that the tertiary referral hospitals also have high quality CT scanners and ultrasound units to allow the provision of the definitive diagnosis.

Apart from the aspect of image quality, which in part remains a subjective factor, the question of rate of throughput is also debatable. It would take a mid–field MRI unit longer to perform exactly the same scanning sequences as a high field unit. However, in everyday practice, mid–field units produce images of diagnostic quality in the same time as the high field units. While it may be argued that the mid–field image is less precise than the high field one, any decrease in image quality may not prevent the making of a definitive diagnosis, and may not affect patient management or outcome. Statements on differences in image quality between scanner types appear generally to be assertions rather than verifiable reports.

With continued technical and software development it may be that the quality of image and throughput at much lower field strengths offered by permanent and resistive systems may prove to be acceptable for many clinical applications. Such lower field systems could potentially have cost attractions and be cheaper to operate and install. In the longer term, some of the cost disadvantages associated with siting high field scanners may decrease with the availability of new types of magnet ('superferric magnets') which have very low fringe magnetic fields(12).

In the Australian assessment program, differences in image quality in particular patients have been noted between the high field and resistive systems with the former having the advantage in head examinations and the latter in examinations of the abdomen. However, the numbers of the different types of units in the program are limited and image quality and clinical usefulness has also depended on the availability of software updates from the manufacturers, suitable maintenance and tuning of the instruments and the level of experience gained by the operators. Contribution of field strength to throughput has been hard to assess, as factors such as different operating schedules at the hospitals, varying case mixes, and software capability also had an influence.

Considerable R&D work is being undertaken in some centres on the development of whole body MR imaging machines of much higher field strength—currently up to 4T—with a view to increasing the quality of the image in the body. Whether the technical, cost and safety difficulties associated with such equipment will be overcome to a sufficient extent to make them attractive in the routine clinical situation is unclear at this stage. The Panel suggests that acquisition of such very high field imaging machines should not be considered for Australia in the foreseeable future except in the context of medical research.

On balance there appears to be a 30 per cent cost differential as regards capital and operating costs between high field and mid field units. It remains a matter of subjective judgement as to whether the additional expense is justified in terms of image quality and improvements to throughput. There is a lack of data showing an effect of magnet field strength on patient management or outcome. The burden of proof lies with those favouring selection of the higher field systems.

Apart from the stated advantages of the ability to perform spectroscopy, the major argument for high field magnets now lies in their the potential to perform cardiac and vascular imaging. While a large amount of research is being done in the application of MRI to cardiac and vascular imaging, at present the required information for such examinations is provided through technologies such as echocardiography and angiography. As the cost of currently used technologies is relatively low, the cost of MRI high field units in such applications needs to be justified on the grounds of patient management, outcome and safety if it is to find a routine place in cardiac imaging.

An unresolved question is the place of the newer permanent magnet systems. The MRI market is coming to resemble the CT and ultrasound markets, with equipment available at varying costs, and with different specifications, but with relatively few data to inform decisions on which types of machine to install.

Other technical developments

The speed and quality of MR imaging have been significantly improved by a number of technical developments over the last five years. There has been an increasing use of surface coils in conjunction with the machines to provide improved imaging for selected areas of the body. The design of these coils has developed considerably and their availability has made a substantial difference to the capability of lower field strength machines.

The development of faster scanning methods in MRI was noted in the first NHTAP report(1) and research on this area has been intensive. As in other areas of the MRI literature, the reports on this topic are many and complex. A number of companies have devoted substantial R & D resources to developing fast scanning sequences and several of these are beginning to become more generally available. As in other areas of MRI development there is often a substantial lag between initial publication of results on fast scanning methods and their routine introduction and application on commercial machines.

In some instances the improved technical capability may be difficult to achieve on a routine basis. The improved patient throughput that use of such methods might achieve could be partially offset by their cost, implications for machine serviceability and the possible need for more comprehensive training for operators.

The use of peripheral gating to overcome motion artefacts, including degradation of spinal images due to pulsation of CSF, has also produced significant advantages in image quality. Cardiac imaging using MRI, including availability of real time images of the beating heart, was referred to in the first NHTAP report. This area has been subject to intensive R & D by the major manufacturers and a number of cardiac imaging packages are becoming commercially available

A further potential development is the evolution of small bore magnet imaging systems for examination of limbs, for example in sports medicine, in view of the major potential for MRI in improving diagnosis of the musculoskeletal system.

A major component of operating cost for the first generation of superconductive magnet systems was expenditure on liquid helium. Cost and availability of this cryogen are of some importance to Australia as all liquid helium has to be imported.

Industry has been unable to develop an effective system for reliquefying helium at MRI sites. Developments in magnet design have led to superconductive MRI scanners that are more sparing of liquid helium and require far less of this material. In addition to cost advantages, there are operational attractions in lower helium consumption as operators of MRI scanners would not be faced so frequently with the task of topping up the magnet cooling system.

The Panel has noted the recent development of so called high temperature superconducting materials. Application of such materials may eventually have implications for magnetic resonance imaging technology but in view of the substantial scientific and engineering problems yet to be overcome the Panel sees no prospect of this for many years.

Contrast reagents

A perceived advantage of MRI over CT is that it does not require the use of iodinated contrast media, commonly used in X–ray techniques, which are associated with a degree of risk to the patient. Most MRI examinations to date have been conducted without recourse to injectable material. However, there has been substantial interest over a number of years in the use of paramagnetic contrast agents in MRI because of an expectation that these will improve the sensitivity and specifity of the technique in particular disease situations. The Australian consensus statement on MRI(13) quoted meningeal disease, meningioma and spinal tumour as examples.

Most of the work so far has been carried out on compounds containing gadolinium and the chelate gadolinium–DTPA is now widely used in the USA following approval by the US Food and Drug Administration. Use of gadolinium has the potential to substantially improve image quality in some examinations, including those from lower field strength machines. At all field strengths there is a hope that certain types of lesion may be more precisely located and delineated when gadolinium or other contrast material is used. Gadolinium–DTPA is not yet generally available in Australia except on an individual patient request basis.

Results obtained using gadolinium–DTPA have been promising in a number of studies, although its place in routine application seems not yet established. There are also occasional areas of difficulty and a study at the Royal Adelaide Hospital noted that uptake by tumour tissue in patients with intracranial neoplasms was disappointing with lack of uniformity in uptake making interpretation difficult(4C).

The effectiveness of gadolinium in MRI will depend on its mode of application. If use of gadolinium is associated with additional MRI scans the cost of an examination would be substantially increased. The view of a number of radiologists participating in the Australian assessment program is that availability of gadolinium would in fact lead to higher patient throughput as the examination would be completed more quickly without the need for extensive investigation.

There is also work proceeding on the development of superparamagnetic contrast agents aimed at particular organs, such as the liver, which will allow a clearer delineation between tissue and lesion. These developments are representative of a new range of contrast agents for MRI usage including such developments as materials with affinity for ischemic tissue for use in cardiac studies. A modification of gadolinium–DTPA specifically binds to calcium ions and development of non–ionic gadolinium chelates gives the potential for greater margins of safety(12).

Cost of MRI

The costs of MRI are dominated by the capital costs of the hardware, particularly in relation to the large magnet that is required. The cost of units in Australia may vary significantly, depending on factors such as exchange rates and arrangements made by individual manufacturers. For the scanners used in the Australian assessment program, equipment costs varied between $2.04M and $3.63M(4). The cost of the most expensive machine, a superconductive scanner, was substantially influenced by movements in the exchange rate. Capital costs of the other two superconductive machines were lower than those for the two resistive systems used in the program.

Site costs in the program were of the order of $0.3M for the two resistive systems and from $0.58M to $0.76M for the superconductive machines.

Capital costs of equipment have decreased since the commencement of the Australian program, and this trend may continue. As an example, the Panel understands that the current costs of mid–field superconductive systems are in the range $1.5M – $2.0M, so that MRI scanners are coming closer in cost to high performance CT machines. There could also be a trend to somewhat lower site costs for superconductive systems with the availability of machines using self shielding magnets.

An emerging aspect of MRI operation is the need for constant updating of software and hardware. From experience to date, upgrade packages costing of the order of $300,000 – $500,000 might be required every three to five years. There will be substantial differences from state of the art performance in both image quality and speed of examination if MRI units are not kept up–to–date. There is a need for funding for the upgrading of equipment on a regular basis.

Data from the MRI assessment indicated that staffing costs were a major proportion of expenditure on MRI services, but that there were wide variations from unit to unit. These variations (from $0.19M to $0.54M a year) reflected different staffing policies at the hospitals and hours of operation, and appeared unrelated to the type of scanner. It would be desirable to consider a standard approach to staffing of MRI units.

Maintenance contracts for MRI units are essential. In the assessment program, annual maintenance costs were between $0.14M and $0.23M for the superconductive machines and $0.10M and $0.11M for the resistive magnet machines. The major variable cost component for the superconductive machines was expenditure on cryogens. For these scanners annual variable costs (including film, electricity and general supplies) ranged from $134,000 to $263,000. The comparative costs for the two resistive were $89,000 and $63,000. Variable costs for more recent superconductive machines are likely to be substantially lower, given the availability of magnets which are more sparing of liquid helium.

The data from the MRI assessment give a range of costs per examination of $513 to $727 (excluding interest), with non–capital related cost per examination between $291 and $416(4). These figures give a broad indication of the cost of MRI examinations in a public hospital setting. It is important to note that they relate to costs under the circumstances of a particular assessment program with specific types of machine. The cost model used makes a number of assumptions and there were wide variations between the different sites. Further detailed consideration would be needed to estimate realistic costs of MRI examinations in other settings, or with newer types of equipment.

Introduction of gadolinium contrast material will also have an effect on costs of MRI services. Overall, it would appear that MRI will remain a significantly more expensive procedure than CT for the foreseeable future.

Safety considerations

Kent and Larson(18) concluded that on the basis of earlier experience and cautious use of MR imaging the technique appears quite safe with no demonstrated side effects for which all patients are at risk. They considered the safety profile for non–contrast MRI to be similar to that of non–contrast CT, better than that for contrast enhanced CT and significantly better than that for invasive CT or myelographic procedures.

The Australian consensus statement(13) noted that:

- the presence of heart pacemakers, ferromagnetic intracranial aneurysm clips, and ferromagnetic foreign bodies in the orbit are the only absolute contraindications to MRI examination;
- metallic surgical prostheses cause local image artefact but have not caused heating or other problems;
- the local environment of the MRI magnet and examination room must be restricted to exclude loose metallic objects so that these do not become projectiles in the magnetic field.
- other than these contraindications and necessary precautions, no hazards to patients from MRI as a result of exposure to magnetic fields and radiofrequency radiation have been demonstrated.

A more recent version of the consensus statement(4E) notes that the risk to the fetus from MRI is unknown, and while no data suggesting hazard have been published, its use in examination of pregnant women should be limited to those situations where its use is essential to medical management and where it can replace the known risks of an alternative test using ionising radiation. Colletti and Platt(14) have suggested that MRI could be used to examine pregnant women under the following conditions:

- where evaluation of the patient's condition cannot wait until after delivery;
- ultrasound cannot provide definitive imaging of the area in question;
- computed tomography would ordinarily be performed on patients with the suspected condition; and
- MRI is known to be efficacious in the suspected condition.

Safety and flexibility of MRI examinations is being assisted by the progressive development of non–ferromagnetic resuscitation, patient monitoring and handling equipment. MRI has a safety advantage over alternative, invasive methods such as myelography and angiography. The absence of ionising radiation associated with MRI is an advantage over X–ray methods seen to be of particular significance in pediatric cases. Doses of paramagnetic contrast material used in MRI are small compared with the doses of iodinated contrast given in many X–ray examinations.

An Australian document on safety of magnetic resonance equipment is currently under development by a working party of the NHMRC.

Operational considerations

The Panel's initial report(1) noted that because of the complexity of the information potentially available from MRI, research on the optimum use of the technology would be required and training would need to be more extensive than was the case with earlier imaging methods. It was suggested that MRI was not an appropriate technique, at its current stage of development, for application by individual clinicians and that MRI units should be operated by a full time team, with ready access to other necessary expertise.

While considerable experience has since been gained in the use of MRI, its optimum application, including interpretation of images, remains a demanding task. Specialised training is essential, and users of the equipment need to be closely aware of the many continuing developments in this area.

Brown has noted that MRI sites in the USA seem to cultivate MRI teams rather than rotating staff in and out of the areas, as it is felt that MRI requires that technologists think about different imaging principles from those used in other modalities. Most sites have found that long term rostering facilitates skill development and helps to maintain imaging quality, as a high level of understanding is often required to achieve good results(12).

The Panel considers that MRI scanners in Australia should be operated by dedicated teams, with appropriate training. This implies a degree of specialisation in this technology for the professionals concerned.

All MRI scanners in Australia will be imported. As is the case with other technologies, it will be essential to ensure excellent technical support from the manufacturers concerned to ensure that operation of the equipment is not prejudiced by long supply lines.

Clinical applications

The initial focus for use of MRI has been in examinations of the head and spine. These applications have continued to dominate and are reflected in the usage patterns of the Australian assessment. Most recent analysis shows that 57 per cent of examinations from the five Australian public hospital MRI units were for head studies with 27 per cent relating to spinal scans.

The numbers of examinations of other regions is beginning to rise and has reached 22 per cent at Royal Melbourne Hospital, covering primarily abdomen and joints. In the Australian assessment data for head examinations the most common presenting symptoms were epilepsy, paralysis/weakness, headache and eye disorder with most common signs being eye disturbance, paralysis/weakness and lack of co–ordination(4).

The literature on clinical application of MRI is very extensive and continues to grow rapidly. The earlier reviews of MRI noted that there were limitations on the data on clinical efficacy then available. For example, the US Office of Technology Assessment (OTA) drew attention to the lack of information on the clinical utility or patient benefit attributable to one diagnostic imaging method or another(15). The Office of Health Technology Assessment commented that the literature of proton MRI is largely a series of impressions, albeit knowledgeable, concerning its ability to depict normal or disrupted anatomic structure(16).

The OTA noted that in the early stages of evaluation of the technology many if not most of the patients that had been studied had appropriately been people with known pathologies, and that it was not necessarily the case that MRI would be shown to have the same sensitivity and specificity when used to image patients with unknown pathology. The OTA noted, however, the rapid improvements taking place in MRI, suggesting that current assessments might underestimate ultimate sensitivity and specificity of the technology in many applications.

Some of the earlier comparisons of MRI with other technologies did not use the state of the art CT and other equipment. Furthermore, many of both the early studies and those more recently reported in the literature refer to small numbers of patients.

The quality of the early assessments of MRI has been strongly criticised by Cooper et al(17) who have pointed to the undesirability of the extremely wide diffusion of MRI, particularly in the USA, before any definitive efficacy studies had been conducted. They also outlined a number of desirable criteria for the assessment of a diagnostic health technology and noted that when matched against these almost no published evaluation of MRI could be regarded as satisfactory.

The most comprehensive assessment of reports on clinical efficacy of MRI is that prepared by Kent and Larson(18) which considered studies conducted before 1987. Kent and Larson noted that in the 80 larger studies they considered there were three major areas of methodologic bias (workup, diagnosis review and test review) that were relevant and that only six of these studies avoided all three biases.

In their main results they concluded that MRI was probably superior to CT for detection and characterisation of posterior fossa lesions and spinal cord myelopathy, imaging in multiple sclerosis, detecting lesions in patients with refractory partial seizures and detailed display for guiding complex therapy as in brain tumours. In other diseases the efficacy of MRI was similar to that of CT.

Kent and Larson considered that use of standards for quality of evidence led to more conservative conclusions than those reports usually describing the potential of MR imaging. They noted that some applications of MRI were confirmed by rigorous studies but others are not well supported by reports free of biases. They also noted that because the field of MRI is changing, review of its clinical efficacy will be need to be revised frequently.

The US National Institutes of Health consensus statement(19) gave a more optimistic outlook on use of MRI. It did not consider the quality of evidence as critically, but was more based on the opinion of senior MRI practitioners.

The Panel notes that, overall, the technical capacity of MRI is covered extensively in the very large literature and that its comparison with other imaging modalities, particularly CT, is becoming better defined. There remain, however, many difficulties in gaining a measure of the effectiveness of MRI, not least those associated with the continued rapid development of the technology, availability of improved versions of older technology (including CT), and limited numbers of cases in most studies undertaken. It is particularly difficult to get a clear assessment of comparative technical capacity under conditions of routine diagnostic usage. Most studies continue to relate to operation of MRI and other technologies in centres of excellence or by instrument manufacturers.

Utilisation of other modalities has been affected by MRI only to a limited extent, on the basis of information available to the Panel. Information on diagnostic impact is limited and tends to relate to studies such as those conducted in Switzerland(20) which resemble the minimum data set approach in the Australian assessment program(3). No such work has been done in terms of quantitative comparison between MRI and CT.

Such studies, which have been based on appraisal of images at the time of examination, have the limitation that while MRI is often rated by radiologists as superior to the alternative imaging method, the incremental diagnostic improvement might be quite small. Useful quantitative comparisons on relative diagnostic impact remain rare. Specialists commonly refer to the useful and novel information provided by MRI on the saggital view of anatomy which was not readily obtained by other techniques. These views may, however, not provide much additional diagnostic information.

As noted by Kent and Larson(18), information on patient management and outcome is sparse. There are methodological and financial difficulties in undertaking work of this sort, especially given the vast range of potential applications of MRI. The work undertaken in Glasgow on comparison of MRI and CT in imaging of posterior cranial fossa lesions(21) is a rare example of a randomised controlled trial design being successfully implemented with a reasonably large number of subjects. Even this study suffered from the difficulties that the machine used was relatively old technology and that the outcome for the imaged patients may not have been fully relevant to the course of the diseases in question.

An indication of radiologists' opinion in a relatively controlled situation is obtainable from the Australian assessment. In the hospitals participating in the Australian study the most common finding on examination was 'MRI abnormal' in 67 per cent of cases with a further 2 per cent of scans equivocal. In 31 per cent of cases no abnormality was detected by MRI at the time of the examination(4).

The high proportion of 'MRI abnormal' in both head (63 per cent) and spinal (73 per cent) examinations reflects the selection of patients considered by referring specialists to have disease and supports their judgements and those of hospital radiologists in giving these cases priority. A lower incidence of 'MRI abnormal' might be expected in situations where access to the technology was less rigorously controlled, particularly if specialist referral was not required(4D,E).

In the Australian study radiologists considered MRI examinations to be indispensable or helpful in 88 per cent of cases. In those cases where comparison was possible with CT (in 67 per cent of head scans and 47 per cent of spinal scans) MRI was considered to be superior in 68 per cent and equally good in 28 per cent. The degree of superiority was not quantified and there are no firm data on the relative benefits of MRI and CT on subsequent patient management in these cases.

The most comprehensive follow–up data in the Australian assessment so far has been the study on 2700 consecutive patients examined by the MRI Unit at the Royal North Shore Hospital, Sydney(22). Data on 2092 patients from this series showed very high MRI accuracy, confirming the radiologists' assessment at the time of the original imaging examination. In terms of proportions of responses received, MRI in this group had significant increment over pre MRI diagnostic accuracy in 64 per cent, was helpful in achieving diagnosis in 74.7 per cent, in assisting patient management in 44.1 per cent and affecting patient outcome in 19.8 per cent.

Australian consensus statement on MRI

In May 1988 the MRI Technical Committee of the Panel developed a consensus statement on current concepts of clinical efficacy of MRI(13). The statement was based on experience gained at MRI Units in the hospitals participating in the Australian assessment and from consideration of relevant overseas data. The statement was intended as a guide to Australian policy and practice on use of MRI, bearing in mind the difficulties and limitations of formal assessment discussed above. The statement has been updated in the Committee's final report(4E).

The view of the Technical Committee is that MRI is at present most effectively utilised as a tertiary, complementary diagnostic imaging modality requested or authorised only by independent specialists for appropriate indications.

In some situations such as examination for syringomyelia MRI may entirely replace other tests, which are substantially less accurate and/or more invasive. The Panel notes that a number of these conditions are relatively rare and would be expected to be managed primarily in the context of a major hospital.

In other situations such as lumbar disc protrusions alternative tests such as CT can be as accurate as MRI which is not usually or initially indicated because of its expense and current limited availability. It is also considered that MRI was not indicated for screening of asymptomatic or mildly symptomatic patients because of the present lack of understanding of the range of normal ageing appearances and lack of correlation with patient management and outcome.

The Technical Committee did not support the view, sometimes put forward in the USA, that MRI should be used as the initial imaging test for detection of most structural microscopic disease of brain and spine. The Committee noted that in the Australian situation limited availability of units, cost of examinations and sometimes limited therapeutic impact would make such an approach inappropriate. In addition, even in applications where it is considered superior to CT, there is limited evidence of the extent of benefit that may be produced, in terms of patient management and outcome. However, future significant changes in costs, accuracy or therapy could require a review of this position.

On the basis of these views and assumptions, the consensus statement makes a number of recommendations on specific applications on MRI particularly in examinations of the brain and spine. These are summarised in table 1.

The statement notes that improvements in technical capability will produce better images and functional data for the cardiovascular system which would then need to be evaluated against other tests. The Council on Scientific Affairs of the American Medical Association has noted that cardiovascular applications are largely in a developmental phase. In this area, MRI overlaps with conventional modalities which frequently provide a more cost effective approach(23).

These opinions give an indication of the present scope of useful application of MRI in routine diagnostic and staging applications. The listing will require further consideration as technical improvements occur and further experience is gained in the use of MRI.

Table 1: Australian consensus statement – opinions on specific applications of MRI

Conditions where MRI is superior to other imaging methods

Head

- Brainstem, posterior fossa, pituitary and midline, foramen magnum skull base tumours. Acoustic neuroma
- Stroke in midbrain and posterior fossa
- Clinically possible/probable multiple sclerosis (but false negative and false positive results can occur)
- Other demyelinating diseases, if clinical selection is possible
- Temporal lobe epilepsy
- CNS infections
- Aqueduct stenosis, Chiari malformation
- Where there is equivocal CT with continued strong clinical indications of disease

Spine

- Syringomyelia and congenital spinal disorders
- Spinal and cord tumours
- Myelopathies
- Post surgical failed back (if imaging is required for management purposes)
- Where there is equivocal CT with continued strong clinical indications of disease

Musculoskeletal

- Localised bone tumours
- Bone necrosis
- Pediatric hip dysplasia
- Bone marrow infiltrations

Conditions where MRI is equivalent to other imaging tests

Head

Brain tumours—for multiple plane display of a diagnosed tumour for surgical and other management

- Supratentorial brain tumours
- Supratentorial stroke
- Staging cancers of nasopharynx, mouth

Spine

- Cervical radiculopathy
- Lumbar disc protrusion

Musculoskeletal

- Knee and joint injuries and diseases

Conditions where MRI is inferior to other imaging tests or unnecessary

Head

- Calcified brain lesions
- Acute stroke management
- Cerebrovascular malformations
- Clinically definite multiple sclerosis
- Other forms of epilepsy
- Head injury (acute trauma)
- Subarachnoid hemorrhage
- Meningeal lesions (unless paramagnetic contrast material is available)
- Orbital disease

Spine

- Evaluation of disc degeneration

Abdomen

- Examination of kidney
- Examination of adrenals
- Examination of liver
- Pelvic lesions
- Chest, mediastinum and heart

Conditions where the value of MRI is uncertain on the grounds of limited clinical effectiveness

- Headache only
- Neck pain only
- Low back pain only
- Dementia without associated neurological signs

Conclusions and recommendations

On the basis of the Australian assessment of MRI and overseas literature, the Panel considers that this technology has been shown to have a useful role in provision of routine diagnostic services and that further distribution of MRI facilities would be appropriate. However, there remain many areas of uncertainty due to the continuing high cost and rapid development of MRI and the doubt as to the degree of benefit its use will produce in the majority of possible applications. Some caution in future policies on procurement and support for this expensive technology therefore seems necessary.

For a proportion of cases examined by MRI units in the Australian assessment, the benefits of MRI were considered to be substantially greater than those derived from alternative imaging methods. In such cases MRI would be the examination of choice.

In some instances the cost of an MRI examination would be of the same order as that of the alternative procedures and associated hospital stay. The Third Interim Report from the assessment(4C) suggested this might be the case for examination of acoustic neuroma, syringomyelia, posterior fossa tumour, pituitary adenoma, cervical spinal myelopathy and temporal lobe epilepsy. These procedures accounted for about 20 percent of the workload at five MRI units. The cost advantages would of course not apply if MRI were carried out in addition to alternative examinations.

For such cases it could be argued that MRI should be available for all in need and that its use could reduce costs and significantly improve quality of life, particularly where it replaced invasive procedures such as myelography.

The Panel considers that instances where MRI has significant and consistent technical and/or cost advantage over other methods may remain in the minority for some time. In a majority of cases, use of MRI would be adding information to that obtained from other imaging methods. The increment in diagnostic yield would be achieved at a higher cost. It would be a matter of judgement as to whether this cost was justified by the additional benefit. The Panel is aware only of limited data on effects of MRI on patient management and outcome by which such judgements might be informed.

Given these considerations, the Panel believes that expansion of MRI facilities in Australia should be cautious. The alternative procedure to MRI is commonly CT. There are at present about 200 CT units in Australia, which provide diagnostic information of high quality. The majority of possible MRI examinations are considered to be either better performed on CT or equal in efficacy to CT.

It would be neither cost effective nor consistent with the present tight financial position in this country, if expensive MRI examinations were to substitute for or, more importantly be added to CT scans of similar diagnostic efficacy.

The Panel therefore recommends that additional usage be initially concentrated in those areas where the comparative advantage of MRI is best established. Since this is mainly in neurological and spinal work, priority should be given to providing access to MRI in hospitals with substantial activity in these areas and accredited for neurosurgical training. Both Sorby(22) and McDonald(24) have suggested such an approach. This would imply a total of about 16 MRI units nationally in neurological teaching hospitals. Eight units are already approved in public hospitals and seven are currently installed or planned in the private sector. The Panel is aware that two private units in NSW are associated with public hospitals, but has no workload data for these installations. It would be desirable to bring them into any national review as soon as possible.

The Panel is unable to say whether this number of scanners represents the optimal provision of MRI services for Australia. However, the Panel is satisfied that a demand of this magnitude may justifiably emerge and that the approach proposed would, under all the circumstances, meet that demand most efficiently. The Panel has no great confidence in overseas data as guide. As pointed out in the report on CT scanning(5), levels of diffusion of diagnostic imaging machines in other countries reflect different health care systems and variations in referral patterns, the availability of alternative approaches to diagnosis and management, medico–legal pressures, patient demand and reimbursement mechanisms. The vast difference in MRI services between the USA and Canadian systems is a case in point.

Location in a specialised, tertiary referral institution would help ensure that operation was by experienced staff and that, for hospital patients, case selection was optimised. However for patients

referred for examination from outside the hospital, criteria of availability would need to be established as some restriction seems necessary to obtain efficient use of MRI.

Three alternative approaches would be:

- MRI available on specialist referral only;
- MRI available on certification (by GP or specialist) of a provisional diagnosis for which it is an appropriate method of imaging;
- or MRI available on certification of the referring doctor and radiologist, after consultation, that MRI is the most appropriate investigation.

The Panel does not see a recommendation on this matter (which has implications for cost reimbursement or other forms of funding) as being within its terms of reference, but would reiterate the need to ensure that this expensive modality is used by specialised personnel in the most cost–effective way.

Some uncertainty remains as to the appropriate type of MRI unit, given the availability of high and mid field superconductive, resistive and permanent magnet systems. On the basis of information available to it, the Panel suggests that there will be no single 'optimum scanner'.

While it has been suggested that tertiary referral hospitals should all have access to high field units, it may be necessary to have only one such unit in each State. Mid field units which are more economical in capital cost, siting and operation could be installed in other hospitals. The Panel is not convinced that the superiority of high field over lower field systems has been clearly established in terms of impact on clinical decision making.

The experience of the Australian MRI Assessment Program has been that resistive MRI units can be operated economically and be clinically effective. The introduction of permanent magnet systems from Japan may allow relatively low cost routine MRI services. It is however too early to determine both the costs and the clinical efficacy of these low field units. Availability of lower cost units may lead to pressures for further diffusion of MRI services.

Whatever units are selected, it is important that both hardware and software are upgraded as changes become available. Experience has shown that substantial improvements in both image quality and patient throughput are possible with existing machines and the costs of upgrades should be included in all operating budgets.

The Panel suggests that further evaluation of the use of MRI in Australia would be desirable, with particular attention being paid to the degree of diagnostic increment obtained in cases of uncertainty and the effects of the technology on patient management. The use of MRI in newer areas of application, such as routine cardiovascular imaging, should be kept under review.

The Panel also recommends that all public sector MRI units be required to routinely collect information on the types of examination they undertake, so that a data base can be developed on the evolving role of the technology. Similar routine data collection at private MRI facilities should be encouraged.

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Acknowledgements

The National Health Technology Advisory Panel is grateful to the following for comments and advice:

Professor BM Tress, Royal Australasian College of Radiologists (RACR)

Mr GAJ McCulloch, Neurosurgical Society of Australasia, Inc.

Dr WA Sorby, Royal North Shore Hospital

Dr M Khangure, Sir Charles Gairdner Hospital

Mr HJ Povel, Medical Applications Pty Ltd

Mr P Leaney, GE Medical Systems Australia

Mr DB Izard, Picker Australia Pty Ltd

Ms AD Gleeson, Solus Medical Imaging Pty Ltd

Mr R Saich, Toshiba (Australia) Pty Ltd

Mr R Shrimpton, Laserex Pty Ltd