ASSESSING THE PLACE OF MRI IN AUSTRALIA

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This paper presents a discussion of the issues, challenges and difficulties of assessing the place of magnetic resonance imaging (MRI), a high cost diagnostic imaging modality, in the context of Australian health care, with reference to the study coordinated by the former National Health Technology Advisory Panel (NHTAP). This material follows from a presentation to an AIH workshop in health economics, held in 1988 and subsequent developments in the NHTAP assessment.

MRI - The nature of the technology

MRI is capable of producing excellent images of soft tissue and demonstrating anatomy in any plane. Unlike many earlier imaging techniques, including CT scanning and nuclear medicine methods, it does not use potentially harmful ionising radiation. Some of the information produced by MRI is unique. There are a number of variations on the technology, often dependent on the type and field strength of the magnet used. Much of the cost of MRI is associated with the need for a large magnet. While the safety of the MRI has not been conclusively demonstrated, no chronic adverse effects on patients or operating staff have emerged as a result of exposure to magnetic and radiofrequency radiation associated with the technique.

MRI first came into use on a research basis in the early 1980's and technical developments since then have been rapid. Any assessment of this technology therefore has to confront the problem of the `moving target'. By the time a lengthy assessment of the place of MRI has been performed, the technology will probably have moved on in terms of hardware, software and new clinical applications.

Assessment issues

Enthusiasm for introduction of MRI was associated with the high quality images it produces and the presumption by some that the superb and unique pictures were necessarily associated with benefits to patients, and in turn that such benefits should be available to all who might need them.

An opposing view, perhaps closer to that held within health authorities, was that here was yet another diagnostic method, and an expensive one (probably costing several hundred dollars per examination), which in all probability would be additive to existing modalities and have no major effect on mortality or morbidity associated with major diseases.

Assessment of the effectiveness of a diagnostic imaging technology such as MRI presents some difficult problems. Although MRI is potentially useful, the earlier technique of CT scanning is a hard act to follow, in terms of diagnostic usefulness, cost and patient throughput. In a proportion of cases, use of MRI will produce only marginal benefit, and benefits will often not be readily quantifiable. Under clinical conditions it is often hard to provide an unequivocal measure of impact of a single diagnostic method. If there is a

significant impact on patient management and outcome, typically this will be complex and often related to quality of life, rather than more obvious measures of morbidity or mortality.

The nature of diagnostic testing implies uncertainty regarding the quality and significance of information available at the time of examination. Such uncertainty will not necessarily be resolved by use of an additional test. The purpose of a diagnostic imaging test is to produce information for another party. The use the other party may make of the information is uncertain. For example, information may be discarded in the light of other evidence. A direct cost-benefit relationship between the cost of a test and improvement in outcome of a patient is difficult to establish.

Methodology of assessment has to be considered in the context of the complexities associated with the diagnostic process. For example Chang(1) in considering the principles of Bayesian analysis, has noted that sensitivity and specificity of a diagnostic method may be functions of time, as progression of the disease state can significantly affect the results obtained. We feel that some caution is needed in applying apparently attractive quantitative assessment methods to tasks such as a broad overview of MRI. Typically, hard data will not be available for Bayesian analysis and variables will not be truly independent.

History of the MRI assessment

The strategy adopted for the assessment, which determined the nature and range of the results obtained, was very much a product of history. The program had its origins in the reports and recommendations of the NHTAP in 1983/84 (2,3) which envisaged assessment of MRI at three sites, with local evaluation teams and strict adherence to protocols. As a result of budgetary pressures and government negotiations, the original NHTAP strategy had to be modified and both the delay in starting and the revised role of the MRI units imposed constraints from the beginning of the assessment (4,5).

A major consequence was that, unlike the first NHTAP proposals, there were to be five MRI units in the program, all now providing routine imaging services, and two in hospitals not originally selected by the Panel as assessment centres. Also, instead of the clear-cut financial arrangements originally envisaged, there was a division of responsibility between Commonwealth and State governments. This led to delays and uncertainties in the provision of funds to the MRI units at the hospitals, in turn creating a degree of mistrust as to government intentions.

This experience illustrates that political influences on health technologies and their assessment may be significant and cannot be ignored. It also points to the need for evaluation strategies to be flexible, to take account of the evolutionary nature of some programs.

Issues for governments

As noted by McDonald (6), at the commencement of the NHTAP evaluation, little was known about the technical performance or clinical use of MRI. Some of the issues for government were the likely cost of this new technology, its realistic range of application, its likely benefits when compared with existing methods, technical performance and significant areas of weakness. These issues have to be seen against the concerns within government circles at the increased expenditure on some health care technologies, and in particular the previous proliferation of CT scanning.

A further point was that available data on MRI had been obtained from more or less unsatisfactory overseas studies, largely in the USA (7). Such studies had been undertaken not only within the framework of a very different type of health care system, but also largely in the climate of research and development work, sometimes in comparison with other technologies which were not used to their optimum level. Furthermore,Kent and Larson have noted that most of the few technically acceptable assessments of MRI were essentially concerned only with the accuracy of the technique (8).

The requirement of government was for a broad assessment of the overall place of this new diagnostic imaging technology. Given the focus of the initial work overseas, and the known technical performance of MRI, it was likely that the initial areas for assessment would be examinations of the head and spine. Even with such restrictions, this left an enormous range of possible types of examinations and disease states for consideration. This general overview was needed relatively quickly to inform the policy process and any discussions with professional bodies, and to minimise effects due to the moving target as MRI evolved technically and clinically.

Mechanism of evaluation and data sets

The assessment was coordinated by a technical committee of the NHTAP which included representatives from radiology departments at each of the five public hospitals in the program. Each hospital collected data over a two year period and these were collated by the NHTAP Secretariat. These data formed the basis of a series of interim reports on the assessment, culminating in a final report from the committee in 1990 (9). The Secretariat closely monitored the data collection process and was able to provide a degree of quality assurance on the results, through its ability to interrogate the hospital units on any points of uncertainty. Major results from the assessment have been summarised by Hailey and Crowe (10).

Three major data sets were collected, covering cost, basic demographic and clinical data on all patients, and a series of more specific studies, dealing with smaller groups of patients with selected disease conditions of particular interest to each centre.

The protocol for collection of cost data was agreed between the MRI technical committee and the accounts section of each participating

hospital, following development of a program by consultants (11). Five major components to cost were considered: depreciation of equipment, salaries, maintenance, variable costs, and indirect costs.

Depreciation was calculated on a straight line basis, equipment over five years and the site over ten years, with appropriate adjustments made in the case of those hospitals where modifications were made to existing buildings, rather than construction of purpose-built sites. The cost model did not include consideration of interest and leasing charges as capital funding was provided through government grants. The cost data provided were audited.

Assembly of this data set was intended as a cost collecting exercise, and did not incorporate more detailed economic analysis. The cost data set represents an extensive collection of information on the operation of MRI scanners at different sites. These data have given a basis for further modelling by governments and others and provided a level of detail not previously available in assessing a major health technology in Australia. There was a degree of difficulty in taking into account the variations between hospitals' accounting practices and their ability to make relevant data available. Differences between the sites included variation in salaries and allowances for staff, maintenance costs which varied with the type of equipment, and expenditure on liquid helium by those units which operated superconductive magnets.

The cost data for two of the units were used to provide a comparison of the cost of MRI examinations with those of alternative procedures for six conditions where the technical committee considered that MRI was the method of choice, with the potential to replace all other diagnostic methods (12). For these conditions, which represented 18 per cent of workload at the units, the analysis suggested that there was little difference between MRI and non-MRI costs and possibly a cost advantage for MRI, if data from the assessment program were compared with Medicare Benefit Schedule fees for the existing procedures. This imperfect comparative model will need following up with more rigorous analysis, and the perceived advantage of MRI could not be accepted without further study. However, this analysis points to the potential usefulness of the cost data obtained through the program.

The minimum data set, collected on each patient examined at the units, included demographic, referral and test indications, operational details, and comparison of image quality in comparison with CT, giving an impression of the impact of MRI in the opinion of radiological staff at the time of examination (13). The minimum data set has been likened to use of a low power view through a microscope (6). This data base included nearly 17,500 examinations, on consecutive cases at each of the centres, and provided an overview of the basic mode of utilisation of this technology within routine clinical imaging departments.

The data base also provided a source of Australian material for synthesis with reports in the literature and a useful resource to plan

studies of specific clinical applications (6). Results of interest included:

- the perceived superiority of MRI over CT in 68 per cent of those cases where CT was available;

- the high proportion of MRI examinations where no abnormality was detected.

- the average of 62 per cent of abnormal results in head examinations, and 72 per cent in spinal examinations, which reflected the prevalence of disease in the groups of patients being examined, and the policy of specialist referral only (10). Such diagnostic yields would not be expected in a situation where MRI was used extensively outside a hospital setting.

For the purposes of the minimum data set, three categories of test indications were included - rule out disease, patient possibly normal; disease present, diagnosis uncertain, test for further information; and diagnosis already established, more information required for treatment. These broad classifications essentially captured the views of specialists on the clinical purpose of a diagnostic method such as MRI.

Most common abnormalities detected in head studies were neoplastic disease, vascular disorder and degenerative disease of white matter. For spinal studies, degenerative disorders, syrinx (cavitation in the spinal column) and neoplasm were most common. It is of interest that the most common MRI report in head studies has been `no abnormality detected'. Such normal findings have potential benefits to patients in cases where suspected disease can be ruled out but are preliminary and may be reversed at final diagnosis.

An example of the more specific studies is that reported by Sorby on 2,810 consecutive examinations at Royal North Shore Hospital, which provided follow-up data on 2,100 cases (14). Sorby has considered in detail the accuracy of MRI in a number of conditions, and has also made an assessment of clinical impact, based on opinion received at three month follow-up from referring clinicians. There are limitations to such an approach, and the potential biases have been discussed in some detail by Sorby. Nevertheless, these data have given a feel for the value offered by the diagnostic technology in the perception of the referring clinicians. Such studies provide a useful initial perspective from which to design more rigorous and detailed investigations.

Specific categories where impact was apparent in this series included 104 cases where use of MRI avoided surgery; 55 where other invasive procedures were avoided; 151 where MRI led to surgery or improved planning of surgery; and 175 cases where a correct diagnosis was established after incorrect results from CT Scanning or other tests.

More than 70 further follow-up studies were undertaken at the hospitals. Most of these related to accuracy of MRI compared with other examinations, including CT and myelography, with more limited data on effects on patient management. Planning of such studies was helped considerably by availability of the minimum data set. They helped to define more closely the accuracy of MRI and its value in patient management in particular situations. Useful negative data were obtained from studies that were abandoned quickly as it became clear that MRI was of limited or no value. For example, in the study of polycystic ovary syndrome, it was found that MRI was not significantly better than ultrasound and that therefore ultrasound was the more cost-effective mode of investigation.

The follow-up studies, opinions of referring specialists and consideration of selected overseas data led to a consensus statement developed by the technical committee (9) which has recently been updated by the Australian Health Technology Advisory Committee (15). The statement represents a collection of opinions on the place of MRI in Australia and is seen as providing a guide to referring physicians and users of the technology. Such overviews of the current role of a technology may be difficult to obtain from the medical literature.

Methodological considerations

Methodologically rigorous approaches for assessment of efficacy/effectiveness of health technologies have been applied most frequently to therapeutic modalities. This is typically true with assessments of pharmaceuticals where there will be the potential for use of randomised controlled designs with large populations and readily defined end points. It is noteworthy that the approach to assessment of diagnostic technologies remains more problematical. The end points in this area are less clear cut than for therapeutic technologies for which outcome measures are more readily defined even if not always easily measured.

With diagnostic technology assessment on various levels has been proposed (16). On the first level, the assessment of accuracy - sensitivity/ specificity-difficulties are often present in that studies will typically measure accuracy relative to another method and both may have changing technical capabilities. Furthermore, as the accuracy of a diagnostic method is dependent on the conditions under which it is used, measures of accuracy typically will provide at best a guide to the efficacy of a technology (benefit under ideal conditions of use), rather than its effectiveness (benefit under average conditions of use).

The level of difficulty in going beyond assessing technical performance of the diagnostic technology to obtain details of how it is used and what effects its use may have on patient status is considerably greater. Measurement of patient status may be particularly difficult, given that the number of cases available may often be limited, the multi-dimensional nature of the clinical decision making process, and the dependence of patient outcome on the

performance of a possibly unrelated therapeutic technology.

The wish for ideality with implementation of an experimental design which emphasises quantification and control may need pragmatic modification to obtain a workable program. Use of a randomised controlled trial (RCT) approach is not appropriate if a broad overview of the efficacy of MRI is required. The RCT cannot show details of the process and there may be practical restrictions limiting its feasibility. Typical areas of constraint will be the level of funding, other commitments of medical and other staff in the program and limited cooperation by some players within the medical system. For example, in the Australian experience, which is shared by others, hospital clinicians were often reluctant to cooperate in any detailed work with the radiology departments in the assessment of MRI. There is a need to tailor assessments of a new health care technology to the technical, logistical and clinical circumstances that prevail.

There may be a need to begin with careful observational study, moving later to more controlled approaches, and perhaps alternating between these levels of analysis. With a technology such as MRI, it is quite impractical to obtain an overview of its value through RCT's. Given the number of applications and rate of change of the technology a virtually limitless number of RCT's would be required, most of which would not stand the test of time. The availability of new software will often lead to substantially improved performance. The RCT of the use of MRI in examination of posterior fossa lesions reported by Teasdale et al (17), which included an economic analysis (18) is in many respects a model for this type of study. However it had the limitation that the MRI scanner used was no longer state-of-the-art. The results from that study, which relate to the efficacy of MRI in one area of application, invite further RCT's rather than providing a definitive statement. Simpler approaches are needed when starting the assessment process.

It is also worth considering the use to which the results of assessment will be put. If the aim is to inform the policy making process on the performance and place of the technology, then typically the data will be expected within a relatively short time frame, so as to help shape budget policy and counter outside pressures. This immediately produces some degree of tension between the policy areas and the experimenters as data may well take time to emerge and to be analysed, particularly if realistic numbers of patients are to be considered.

Developments since the completion of the trial

Following completion of data collection, the NHTAP prepared a report on magnetic resonance imaging services as a follow-up to its original assessment, drawing extensively on the material that had been obtained during the trial (19). Major recommendations of the report included that priority be given to providing access to MRI at hospitals with substantial neurosurgical responsibilities; that MRI be used by specialised personnel in the most cost-effective way, that costs of

upgrades be included in all operating budgets, that development and use of MRI be kept under review (particularly in newer areas of application); and that all public sector MRI units be required to routinely collect information on the examinations undertaken so that a data base could be developed on the evolving role of the technology. The report also drew attention to the consensus statement that had been developed during the course of the trial.

This report on magnetic resonance imaging services had a significant effect on the policy process and the broad thrust of the recommendations was taken on board by the Commonwealth Government in the recent budget. Support was announced for further installation of public sector scanners with emphasis on the neurosurgical applications flagged by the NHTAP. The Commonwealth Department of Health, Housing and Community Services is also seeking to put in place the routine collection of data by public sector units.

A further feature since the completion of the trial has been the diffusion of MRI scanners in the private sector, despite the absence of reimbursement for examinations they undertake. The relationship of the assessment to operation of these private sector units is unclear, but it would appear that their caseload will bear only a limited relationship to the priorities identified by the NHTAP.

The contrast agent gadolinium-DTPA was used only to a limited extent during the assessment (9), as marketing permission had not been obtained in this country. This material is now available commercially in Australia and usage is becoming widespread. A discussion paper prepared by the AIH on use of this material (20) reached the conclusion that Gd-DTPA provides a useful extension to MRI for some types of examination, but that its effectiveness in terms of impact on patient, management and outcome requires further definition. Costs of Gd-DTPA nationally might range from $0.4M per year in the short term to perhaps $10M a year after further diffusion of MRI, if used in a high proportion of examinations. The report included indications of the type of examination where Gd-DTPA was considered appropriate, based on the early experience with this material in Australian hospitals.

Capital costs of MRI equipment have decreased since the trial was undertaken, and there have been progressive improvements in software. Operating costs of machines with superconductive magnets are also lower, as the designs are more sparing of cryogens. Scanners based on permanent magnets offer further reduction in costs, though their performance in comparison with other types of machines is still not fully defined.

There are indications that applications of MRI can be expected to widen. Increasing interest is being expressed in the wider use of MRI for examination of joints. Many recent MRI scanners are being made available with options for angiography examinations and the application of the technique to cardiovascular imaging may get increased attention in the future. All of these areas deserve to be

considered critically and proper assessments undertaken. As with other major technologies, MRI provides a good example of the need to follow up initial assessments with further evaluation.

Achievements and limitations of the Australian program.

The MRI assessment program achieved a planned, rational introduction of this technology into Australia, with provision of detailed cost and utilisation data, useful and emerging information on the accuracy of the technique and its effects on patient management and publication of a consensus statement. Not least, the assessment helped to define the place of MRI in the diagnostic sequence. These data proved useful both to clinicians and to those planning to acquire MRI equipment. Baddeley (21) has noted the value to medical practitioners of the good information produced on effectiveness and cost.

There has also been a valuable educational process which has led to productive interaction between specialists, evaluators, bureaucrats and others (6) and a stimulation of interest in the assessment of health care technologies.In comparison with assessments of MRI undertaken in other countries, the range of data obtained in the Australian program has been unusually broad. Other assessments have not combined appraisal of costs with both basic utilisation and clinical studies and follow-up investigations. The results from the Australian assessment have been well received internationally.

The complex data from the program have been an important input to the policy process, although clearly there are limitations as to how far policy areas are able to influence usage of the technology, particularly in the private sector.

Limitations of the program in a methodological sense have been considered above and include some of those discussed in critiques of diagnostic technology assessments (8). The absence of randomised populations and problems of limited follow-up have to be viewed in the context of organisational and funding constraints, and the wish to obtain data on large numbers of patients and types of application.

We suggest that there may be a need to consider the adequacy and limitations of economic evaluation when dealing with complex diagnostic technologies. Further work is clearly desirable on measurement of effects of a diagnostic technology on quality of life. Data will usually be limited and difficult to obtain, outcomes may not be easily defined or independent of other technologies. Finally, the insight produced from more detailed evaluation of discrete areas of application may be of limited value to the policy maker seeking broad guidance as to the place of a method such as MRI in the health care system.

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