NHS
Purchasing and Supply Agency

Centre for Evidence-based Purchasing

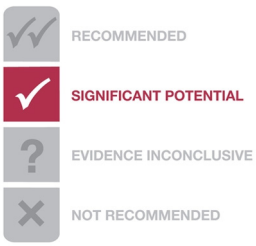
Evidence review

Diffusion-weighted magnetic resonance imaging and competing imaging technologies for the diagnosis of stroke and transient ischaemic attack (TIA)

CEP 08003

April 2008

Verdict



Informing procurement - Encouraging innovation

Contents

Summary

The product

Diffusion-weighted imaging (DWI) is an application package that is either incorporated in the core Magnetic Resonance Imaging (MRI) scanner software or added as a cost option.

Field of use

DWI shows greater sensitivity and specificity than non-contrast CT in the study of ischaemic lesions of TIA patients. DWI can identify cerebral ischemia in the brain minutes after a stroke due to a rapid decrease in the apparent diffusion coefficient (ADC) in tissues that have suffered cytotoxic oedema. DWI has also shown great potential in excluding haemorrhage in stroke and identifying salvageable brain tissue, when combined with other MRI techniques. Currently, DWI is also used in a clinical setting for the study of intracranial tumours. Future applications of DWI may range from prostate cancer to neurological disorders. A number of freely available review articles and online tutorials cover the principles, methodology and application field of DWI [1,2].

National guidance

The National Stroke Strategy [3] aims to raise public awareness of stroke and transient ischaemic attack (TIA) symptoms and improve the speed of diagnosis and treatment. The National Institute for Health and Clinical Excellence (NICE) is currently developing clinical guidelines for the diagnosis and acute management of stroke and TIA, with an expected publication date of July 2008 [4]. The National Clinical Guidelines for Stroke, published in 2004 by the Royal College of Physicians [5], suggest that MRI, including DWI, is considered to be the most suitable imaging strategy for TIA and minor stroke. It is expected that the NICE guidelines will extend this suggestion to a recommendation.

Evidence reviewed

This review has been conducted based upon reported clinical evidence of the use of DWI and other competing imaging technologies for diagnosis of TIA and stroke. Evidence reviewed concentrated on original publications conducted on human subjects for the period 2000-2007. Studies were examined on the basis of clinical diagnostic outcomes for each imaging modality (specificity and sensitivity), study design and relevant economic evidence.

CEP's verdict – **Significant potential**

Based on the evidence reviewed in this report and on national guidelines, DWI shows significant potential in the study of minor stroke and TIA. In addition, DWI combined with other MRI techniques is currently superior than non-contrast CT for the exclusion of stroke mimics and shows significant potential in excluding haemorrhage and identifying patients who may experience a better clinical outcome through pharmacological treatment. However, it should be noted that DWI may not be suitable for all patients on account of safety restrictions and there may be considerable practical problems with validating MRI patient suitability within the time-window required for acute TIA and stroke scanning.

Introduction

Product description

Diffusion-weighted imaging (DWI) is a clinical application package in Magnetic Resonance Imaging (MRI). The majority of MRI scanners currently offered by manufacturers are equipped with a basic-level DWI package, which is generally adequate for TIA and stroke imaging. DWI may be offered as a cost option for MRI scanners not supplied with it and most scanners equipped with the basic-level package can be optionally upgraded to offer more advanced DWI methodologies and analysis. For a market review on DWI, please refer to a CEP buyers' guide for DWI [6].

National guidance

The National Stroke Strategy [3], published on 5th December 2007, is a 10 year plan which aims to raise public awareness of stroke and transient ischaemic attack (TIA) symptoms and improve the speed of diagnosis and treatment. The National Institute for Health and Clinical Excellence (NICE) is currently developing clinical guidelines for the diagnosis and acute management of stroke and TIA, with an expected publication date of July 2008 [4]. The latest draft of the guidelines makes specific reference to DWI, recommending that:

> People with a suspected TIA who require brain imaging (i.e. those in whom vascular territory or pathology is uncertain) should undergo MR with DWI (magnetic resonance with diffusion-weighted imaging) except where contraindicated, in which case CT (computed tomography) should be used.

The National Clinical Guidelines for Stroke, published in 2004 by the Royal College of Physicians [5], suggest that rapid MRI referral (within 24 hours of experiencing symptoms) is recommended for all patients seen acutely after a TIA or minor stroke for whom there is uncertainty regarding the diagnosis. MRI, including DWI, gradient echo imaging (GRE) and magnetic resonance angiography (MRA) are considered to be the most useful in imaging for TIA and minor stroke.

Purpose and structure of this report

The purpose of this report is to inform those making purchasing decisions by providing a synopsis of existing evidence on the role of DWI in stroke and TIA imaging. Vascular (carotid) imaging has been excluded from this report, as it is not an application field for DWI.

The evidence review is divided into two sections to reflect the different patient pathways and diagnostic needs. The first section presents evidence related to TIA and minor stroke and the second section presents evidence related to stroke. Abstracts of the reviewed evidence and related documents (e.g. full article and comments) can be accessed using the internet links provided at the end of this report.

Stakeholder engagement

A number of stakeholders and clinical experts were approached for comment and their responses have been incorporated in this report.

Methods

Sources

A comprehensive search for original articles comparing DWI to other imaging technologies was conducted on the following databases for the period 2000-2007:

Medline (www.pubmed.gov)
Centre for Reviews and Dissemination (http://www.york.ac.uk/inst/crd/)
Agency for Healthcare Research and Quality (http://www.ahrq.gov)
Canadian Agency for Drugs and Technologies in Health (www.cadth.ca)
Cochrane Library (http://www.cochrane.org/)
Trip Database (http://www.tripdatabase.com)
National Guideline Clearinghouse (http://www.guideline.gov)
National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk)

The selection of publications concentrated on clinical human studies. The studies were chosen following a review on the methodology used, clinical trials, diagnostic accuracy and outcomes. In addition, the reference list for each article was examined and additional relevant articles reviewed.

Search terms

The following search strategy was used:

S1: (magnetic resonance imaging OR MRI or MR or magnetic) AND diffusion

S2: diffusion magnetic resonance imaging OR DWI OR diffusion-weighted OR diffusion weighted

S3: (CT OR computed tomography) AND (perfusion OR angiography)

S4: Positron Emission Tomography OR PET

S5: Single Proton emission Computed Tomography OR SPECT

S6: ischemia OR ischaemia OR ischemic OR ischaemic OR stroke OR TIA OR Transient ischaemic OR Transient ischemic

S7: (S1 OR S2 OR S3 OR S4 OR S5) AND S6

Inclusion and exclusion criteria

Studies were included if they met the following criteria: human studies of stroke or TIA, using CT (non-contrast, perfusion, angiography) and DWI (alone or combined with other techniques), performed in hyper-acute, acute and sub-acute phases. In addition, factors such as presence of blinding, time between different imaging modalities, time from onset of stroke to imaging and presence of randomised tests were recorded. No abstracts were used.

Transient ischaemic attack and minor stroke

Definition and epidemiology

Transient ischaemic attack (TIA) has been defined as an acute transient focal neurological deficit caused by vascular disease that clears completely in less than 24 hours [7]. However, recent studies suggest that a more accurate definition of TIA would be that of a brief episode of neurological dysfunction caused by focal brain or retinal ischaemia, with clinical symptoms typically lasting less than one hour and no evidence of acute infarction [8].

Minor stroke is a neurological event resulting in slight impairment of neurological function (speech, motor, or sensory skills) that may completely resolve within a few days [9]. Although minor stroke may be identified on the basis of clinical scores and scaling systems, it is also often diagnosed on the basis of clinical judgement, taking into account type and severity of the neurological deficit within the context of an individual patient's age and underlying health [10].

TIA affects 35 people per 100,000 of the population in the United Kingdom each year [5] and it has been shown that patients who have suffered a TIA or minor stroke are at high risk of recurrent stroke and TIA [11,12].

Goal of brain imaging in TIA

The goal of brain imaging in TIA and minor stroke is to exclude other conditions with similar symptomatology (stroke mimics) and determine the presence and location of ischaemic lesions as well as the vascular territory involved, all of which may be useful in identifying cause, determining patient management and guiding stroke-preventive therapy [4,13,14].

Role of DWI and competing imaging technologies in TIA and minor stroke imaging

It has been established that the sensitivity and specificity of DWI is superior to Computed Tomography (CT) in the detection of ischaemic lesions, particularly if DWI is performed in the acute phase (less than 24 hours from symptom onset) [15,16,17,18]. Even in the sub-acute phase (more than 24 hours from symptom onset), it has been shown that ischaemic lesions remain visible [19,20,21,22,23]. The sub-acute time frame is particularly pertinent to patients who delay seeking medical attention by a few days, whereafter it may be difficult to obtain a clear history, diagnose the ischaemic event or identify the vascular territories involved.

The presence of DWI abnormalities is highly correlated with ischaemia, but their absence does not rule out TIA or minor stroke [24]. False-positive DWI signals have also been related to several stroke mimics, such as seizure or tumours. However, the clinical history and the appearance of these signals in conventional MRI techniques should allow for exclusion of these stroke mimics [41]. In addition, several studies have shown that the presence of DWI abnormalities can be a predictor of stroke and recurrent TIA [24,25,26,27,28,29,30].

Recent work has indicated that ischaemic lesions identified with non-contrast CT can also be used as predictors of recurrent TIA and stroke [31]. It has also been shown that perfusion-CT and CT-angiography can be comparable to DWI in the assessment of ischaemia in the hyper-acute and acute phases [32,33,34,35,36,37]. However, further work is required to demonstrate the potential role of CT in the study of ischaemia in the sub-acute phase. This is because it is likely that most patients currently seek medical attention within this phase.

Stroke

Definition and epidemiology

Stroke can be described as an acute neurological deficit due to sudden disruption of blood supply to the brain. Stroke is caused by either an occlusion of an artery (ischaemic stroke or cerebral ischaemia/infarction) or rupture of an artery leading to bleeding into or around the brain (haemorrhagic stroke or intracranial haemorrhage) [41]. Every year, an estimated 150,000 people in the UK have a stroke [42]. The majority of strokes, estimated at approximately 80%, are of the ischaemic type [43,44]. Stroke is the third most common cause of death in the UK, accounting for 9% of deaths in the male population and 13% in the female population [42,45]; stroke is also a leading cause of severe adult disability.

Goal of brain imaging in stroke

The primary goal of brain imaging is to differentiate between ischaemic and haemorrhagic stroke and to exclude stroke mimics, thereby helping determine an appropriate treatment approach with pharmacological therapy or surgical intervention [4,5,41]. An emerging goal in acute stroke care is to determine the extent of brain tissue that is viable and thus amenable to therapy.

Role of DWI and competing imaging technologies in stroke imaging

Computed Tomography (CT) is widely accepted as the gold standard for excluding intracerebral haemorrhage and identifying patients suitable for thrombolytic therapy [5,46,47]. However, recent studies have shown that the combination of DWI with other MRI techniques can be at least as sensitive as CT in the detection of intracerebral haemorrhage, even in the hyper-acute phase [48,49].

MRI is particularly important in the evaluation of acute stroke patients displaying unusual presentations, stroke varieties and uncommon aetiologies, or in whom a stroke mimic is suspected but not clarified on CT [50]. However, in these cases DWI is not used in isolation but rather combined with other MRI techniques.

DWI also provides additional information on tissue viability when combined with perfusion-weighted imaging (PWI). Salvageable brain tissue, defined as the ischaemic penumbra, can be identified as the area where the DWI signal is normal and PWI signal abnormal (DWI-PWI mismatch). In fact, recent studies have demonstrated that patients with DWI-PWI mismatch

who have undergone pharmacological treatment experienced a better clinical outcome [51,52].

Perfusion-CT and CT-angiography have also been suggested as alternatives to the use of DWI and PWI for the identification of the ischaemic penumbra [33,34,35,36,37], although concerns have been expressed over the associated increase in radiation exposure [38]. Further research, including randomised, multi-centre trials, is required to establish the correlation between CT and MRI -based applications. Positron emission tomography (PET) and single proton emission computed tomography (SPECT) have also shown potential in identifying tissue viability in stroke [39,40] but the wider adoption of these modalities in stroke care is currently restricted by the limited installed base and the higher operational costs.

Cost of stroke and TIA

A detailed study by the Division of Health and Social Care Research project team at King's College London showed that the cost of stroke to the economy in the United Kingdom is approximately £7 billion a year [53]. The direct cost to the NHS is about £2.8 billion a year and annual costs associated with informal care, disability and loss of productivity are around £4.2 billion. In the above study, TIA was included in the calculations for diagnostic, inpatient, outpatient and outpatient drug costs but not in the community care and informal care calculations, given the short-term nature of TIA symptomatology.

Cost effectiveness analysis

The Health Technology Assessment on stroke presented strong evidence to determine the cost-effectiveness of CT scanning [54]. The study used a decision model composed of 12 care strategies to predict the cost-effectiveness of CT scanning but did not apply the model to MRI, on account of lack of availability and greater cost than CT. More recent studies have confirmed the continuous lack of availability of MRI for stroke imaging in the United Kingdom and across Europe [55,56]

The Canadian Agency for Drugs and Technologies in Health conducted two systematic reviews of the economic evaluations and cost-effectiveness of CT and MRI for selected clinical disorders, including stroke. No strong evidence on the use of MRI in the management of acute stroke was reported. The Agency reviewed three studies that assessed the impact of CT on diagnosis and cost utility of CT scanning and rated the papers as presenting a limited review of evidence. All reported studies concluded that immediate referral to CT scanning was the most cost-effective strategy [57].

In a recent study based at a general district hospital in the United Kingdom, DWI was implemented as the first-line neuroimaging test for inpatients with clinically suspected acute stroke [58]. The study showed that DWI was both feasible and sustainable in the setting of a district general hospital, there were no significant differences in the examination times between CT and MRI and most clinicians felt that DWI was a significant improvement to stroke services.

The average cost of MRI and CT according to the 2008/09 Payment by Results tariff is £169 and £131, respectively [59]. There are currently no studies showing how improvements in patient care provided by the advantages of MRI can balance the increased imaging costs compared to CT. However, a recent Health Technology Forecast report by the ECRI Health Technology Assessment Information Service in the United States of America suggested that the cost difference can be offset by replacing single imaging tests with multimodal MRI, thus improving diagnostic efficiency and treatment [60].

Overall, there is no evidence on the cost-effectiveness of DWI in stroke and TIA, which could be used to assess economic factors associated with the introduction of this technique in routine clinical examinations.

Conclusions

There is strong evidence that DWI can be useful for TIA and minor stroke patients in identifying cause, determining patient management and guiding stroke-preventive therapy. The evidence on the role of perfusion-CT and CT-angiography in TIA studies is currently limited to the hyper-acute and acute phases and further evidence is required for the sub-acute phase, which describes a more likely clinical case for TIA patients.

Non-contrast CT is currently the gold standard for the exclusion of intracerebral haemorrhage in stroke and the identification of patients suitable for thrombolytic therapy. However, recent strong evidence suggests that DWI combined with other MRI techniques can be as sensitive as CT.

DWI combined with other MRI techniques can be superior to non-contrast CT in identifying stroke mimics. However, perfusion-CT and CT-angiography may potentially play a future role in identifying stroke mimics that are unclear in non-contrast CT studies.

There is evidence that DWI combined with PWI can identify patients who will experience a better clinical outcome through pharmacological treatment of acute ischaemic stroke. Further research is required to establish that perfusion-CT and CT-angiography can provide equivalent prognostic information. PET and SPECT have also shown potential in the identification of brain tissue viability, but the wider adoption of these modalities in the clinical field is currently restricted by the limited installed base and the higher operational costs.

There is currently no data regarding the cost-effectiveness of DWI for the diagnosis and management of stroke and TIA patients. Although DWI in itself is a very fast imaging technique, it is nevertheless likely to be combined with other MRI techniques, for example PWI, which will inevitably increase the total examination time when compared to CT imaging. However, the increased sensitivity and specificity offered by MRI may also decrease the need for repeat imaging and improve overall diagnostic efficiency and treatment.

It should be noted that MRI studies, including DWI, may not be suitable for all patients on account of safety restrictions (e.g. pacemakers) and there may be considerable practical problems regarding the validation of MRI suitability for use within the time-window required for diagnosis of TIA and stroke in the acute phase. On the other hand, potentially alternative dynamic CT studies, such as perfusion-CT and CT- angiography, can impart a high radiation dose to patients.

Acknowledgements

The authors would like to acknowledge the following for their comments, feedback and suggestions:

Dr Dennis P. Briley, Stoke Mandeville Hospital, Aylesbury, Buckinghamshire

Professor Martin M. Brown, Institute of Neurology, University College London

Professor Alistair M. Buchan, John Radcliffe Hospital, Oxford

Professor Gary A. Ford, Royal Victoria Infirmary, Newcastle

Professor Peter M. Rothwell, Stroke Prevention Research Unit, University of Oxford

Professor Joanna M. Wardlaw, Department of Clinical Neurosciences, University of Edinburgh

Department of Health, Stroke Team (Mrs Lucy Holdstock, Mrs Helen O'Kelly and Mrs Sue Dodd)

The Society and College of Radiographers

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Evidence review: Diffusion-weighted magnetic resonance imaging and competing imaging technologies for the diagnosis of stroke and transient ischaemic attack (TIA)

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