Does early magnetic resonance imaging influence management or improve outcome in patients referred to secondary care with low back pain? A pragmatic randomised controlled trial

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Executive summary

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Objectives
To establish whether the early use of sophisticated imaging techniques such as magnetic resonance imaging (MRI) or computed tomography (CT) influences the clinical management and outcome of patients with low back pain (LBP) and whether it is cost-effective.

Design
A pragmatic multicentre randomised controlled trial using a standard two parallel group approach incorporating an economic evaluation. For a subgroup of trial participants, a controlled ‘before and after’ approach was used to assess the impact of ‘early imaging’ on clinicians’ diagnostic and therapeutic confidence.

Setting
A total of 14 hospitals in Scotland and one in England over a 24-month period (seven teaching hospitals and eight district general hospitals).

Subjects
The 782 participants had been referred by their general practitioner to a consultant orthopaedic specialist or neurosurgeon because of symptomatic lumbar spine disorders, and the specialist was clinically uncertain about the need for imaging.

Intervention
Of the eligible patients who consented to participate, 393 were randomly allocated to ‘early imaging’ (MRI or CT as soon as practicable) and 389 to ‘delayed, selective imaging’ (no imaging unless a clear clinical indication developed). Choice of imaging modality and patient management plans was at the discretion of the referring clinician.

Main outcome measures
Participants completed a baseline questionnaire containing the Short Form with 36 Items (SF-36), Aberdeen Low Back Pain score (ALBP score) and the EuroQol (EQ-5D). Postal questionnaires were completed after 8 and 24 months. Patient management was determined retrospectively by case note abstraction and from patient questionnaires. In the study of diagnostic impact, clinicians completed assessment forms at the time of trial entry and at follow-up appointment.

Results
Participants in both groups reported an improvement in health status at 8 and 24 months with the ‘early imaging’ group having statistically significantly better outcome. After adjustment for baseline score and other factors, the mean differences at 24 months were 3.62 points [95% confidence interval (CI) –5.92 to –1.32; p = 0.002] for the ALBP score and 0.057 (95% CI 0.013 to 0.101; p = 0.01) for the EQ-5D. The ‘early imaging’ group also had significantly greater improvement in most subscales of the SF-36 at 8 months, but only for the Bodily Pain subscale at 24 months.

Other than the proportion of participants receiving imaging (90% versus 30%), there were few differences between the groups in the management received throughout the 24-month follow-up. The total number of outpatient consultations in the two groups was similar although more people in the ‘early imaging’ group had return outpatient appointments during the 8-month follow-up (p < 0.001).

Clinicians’ diagnostic confidence, between trial entry and follow-up, increased significantly for both groups with a greater increase in the ‘early imaging’ group (p = 0.01).

The cost of imaging was the main determinant of the difference in total costs between the groups and it was estimated that ‘early imaging’ could provide an additional 0.07 quality-adjusted life-years (QALYs), at an additional average cost of
£61 over the 24-month follow-up. Using non-imputed costs and QALYs but adjusted for baseline differences in EQ-5D score, the mean incremental cost per QALY of ‘early imaging’ was £870. The results were sensitive to the costs of imaging and the confidence intervals surrounding estimates of average costs and QALYs.

Conclusions
The early use of sophisticated imaging does not appear to affect management overall but does result in a slight improvement in clinical outcome at an estimated cost of £870 per QALY. Imaging was associated with an increase in clinicians’ diagnostic confidence, particularly for non-specialists.

Implications for health care
The main resource implication is the cost of imaging. Decisions about the use of sophisticated imaging in this context will depend upon judgements about the value of the observed differences in outcome and whether these justify the extra costs.

Recommendations for research
Further research is required to determine if more rapid referral to sophisticated imaging and secondary care is important in the acute episode and whether the use of imaging would be more beneficial for particular categories of LBP.

Publication
The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’ that is being developed to improve the evidence of clinical practice throughout the NHS.

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Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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