Cost-effectiveness of lumbar spine radiography in primary care patients with low back pain

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of lumbar spine radiography in patients with low-back pain.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis; cost-benefit analysis.

Study population
The study population comprised patients with low-back pain lasting at least 6 weeks in the 6 months prior. Patients were excluded if potentially serious spinal pathologies were suspected, if they had chronic low-back pain (more than 6 months), or if they had had lumbar spine radiography in the preceding 12 months. Pregnant women or those planning a pregnancy were also excluded.

Setting
The setting was primary care. The economic study was carried out in the East Midlands area in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered from November 1995 to January 1999. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were performed in the preliminary phase of the study. These suggested that 388 patients (in both arms of the study) were needed to achieve a difference in the mean Roland score of 1.5, with 90% power at a 5% significance level. The patients were identified at 52 practices during the study period. A total of 421 eligible patients were identified. Of these, 210 were enrolled into the intervention group and 211 into the control group. In the intervention group, the median age was 39 years (interquartile range, IQR: 31 - 45) and 42.9% of the patients were men. In the control group, the median age was 39 years (IQR: 31 - 46) and 39.9% of the patients were men.
Study design
This was a prospective randomised controlled trial that was carried out in 52 practices across UK. A nurse visited the patients at home after invitations were sent to all eligible patients at the study centres. The patients were then randomly assigned by opening a sealed opaque envelope containing the treatment group allocation. Block randomisation was carried out using blocks of 20 to ensure the numbers between the two groups were equal. A member of the research group who was not involved in patient allocation provided the computer-generated allocation schedule. The length of follow-up was 9 months.

Seven patients in the intervention group and 5 patients in the control group were lost to follow-up. In addition, 8 patients in the intervention group and 7 patients in the control group withdrew from the study. Therefore, 195 patients in the intervention group and 199 in the control group (94%) completed the trial, although 171 intervention group patients and 26 control group patients had spinal lumbar radiography. The satisfaction questionnaire at the end of the follow-up was available for 42 patients in the intervention group and for 47 patients in the control group. The outcome assessment was not blinded.

Analysis of effectiveness
It appears that the analysis of effectiveness has been restricted to those patients whose data were available at the end of the follow-up. The primary outcome measure used in the effectiveness study was the Roland disability score. The secondary outcomes were a visual analogue pain scale (ranging from 0 to 5), the EuroQol, and satisfaction with care (measured using a self-completed questionnaire). The two groups were comparable at baseline in terms of their age, gender, and symptoms of low-back pain.

Effectiveness results
There were no statistically significant differences between the groups at 9 months in terms of:

- the median Roland score, 3 (IQR: 0.7) in the intervention group versus 2 (IQR: 0.6) in the control group, (p=0.06);
- the median pain scale, 1 (IQR: 0.2) in the intervention group versus 1 (IQR: 0.2) in the control group, (p=0.17); and
- median EuroQol, 0.8 (IQR: 0.69 - 1) in the intervention group versus 0.8 (IQR: 0.73 - 1) in the control group, (p=0.28).

The overall median satisfaction score changed from 19 to 21 in the intervention group and from 20 to 19 in the control group, (p<0.01). This means that the intervention patients were more satisfied than the control patients with the care they received.

However, an analysis of sub-categories suggested that the radiography group was no more likely than the control group to have been reassured or less worried about serious disease as a cause of low-back pain.

Clinical conclusions
The effectiveness analysis showed that there was no statistically significant difference in terms of functional outcomes between the two groups. However, the intervention patients were more satisfied overall with the care they received than the control patients were.

Measure of benefits used in the economic analysis
Two different summary benefit measures were used in the economic analysis. In the cost-effectiveness analysis, the main benefit measure was the satisfaction score. This was obtained directly from the effectiveness study. In the cost-benefit analysis, the main benefit measure was the valuation of reassurance from radiography. This was estimated using the willingness to pay approach, where patients were asked directly how much, hypothetically, they would be willing to pay for the risk of radiation from radiography to be reduced to zero and for the reassurance from radiography.
Direct costs
Discounting was not performed due to the short time horizon of the analysis. The unit costs and the quantities of resources use were not provided separately. The health services in the economic evaluation were radiography, inpatient admission, outpatient attendance, general practitioner visits, physical therapies, medication, special equipment purchased, and travel expenses of the patient or companion. The cost/resource boundary of the analysis reflected a societal perspective. Resource use was estimated using actual data derived from the sample of patients who were included in the effectiveness study. The costs were estimated from multiple unspecified sources. The price year was not stated.

Statistical analysis of costs
Standard statistical tests were performed to test the statistical significance of differences in the estimated costs.

Indirect Costs
As in the analysis of the direct costs, no discounting was performed due to the short time horizon of the analysis. The unit costs and the quantities of resources used were not reported separately. The categories of costs considered were work losses of the patient or companion, practical help, extra expenses incurred, social security payments, and loss of productivity for the employer. An economic evaluation of the risks from radiation was also carried out using the willingness to pay approach, as in the estimation of the economic value of the reassurance from radiography. The cost/resource boundary was that of society. Resource use was derived using data extracted from case notes. The source of the unit costs was not reported. The price year was not given.

Currency
UK pounds sterling ( ).

Sensitivity analysis
Sensitivity analyses were not performed.

Estimated benefits used in the economic analysis
In the cost-effectiveness analysis, the mean satisfaction score was 20.71 in the intervention group and 18.61 in the control group. Therefore, the difference was 2.1 in favour of the radiography group. In the cost-benefit analysis, the estimated valuation of reassurance from radiography was 30.

Cost results
The mean total direct cost was 150.04 in the intervention group and 109 in the control group, (p<0.001).

The mean total indirect cost was 449 in the intervention group and 392 in the control group, (p=0.373).

The mean total direct and indirect costs were 590 in the intervention group and 507 in the control group, (p<0.001).

Synthesis of costs and benefits
An incremental cost-effectiveness ratio was calculated to combine the costs and benefits of the two interventions. The additional cost for an additional unit of satisfaction was 19.54. The net economic impact associated with radiography (sum of the direct cost, indirect cost and perceived value of risk of radiation, minus the valuation of reassurance from radiography) was 115 extra per patient. A bootstrap approach was carried out to address the issue of uncertainty in the results of the analysis.

Authors' conclusions
Lumbar spine radiography led to improvements in patient satisfaction, but did not improve other clinical outcomes in patients with low-back pain. However, the increased satisfaction was achieved at a cost that society might not be willing to pay.

**CRD COMMENTARY - Selection of comparators**

The authors stated that no routine referral for lumbar spine radiography was selected as the basic comparator because it represented the usual care approach in primary care for patients with low-back pain. You should decide whether it represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**

The analysis of effectiveness used a prospective randomised trial, which was appropriate for the study question. The methods of randomisation and sample selection were reported. The study was powered to detect statistically significant differences in the primary outcome measure. However, it was unclear whether the sample size was appropriate for the analysis of secondary outcome measures. The study sample was selected from several primary care general practices and no strict selection criteria were used. Therefore, the study sample is likely to have been representative of the study population. The two groups were well balanced at baseline in terms of their demographic and disease-related characteristics. These issues tend to enhance the internal validity of the analysis. However, some patients were lost to follow-up. In addition, the valuation of the outcomes was limited to those patients who responded to the questionnaire, which represented a small group in relation to the initial sample size.

**Validity of estimate of measure of benefit**

Two summary benefit measures were used in the two types of economic evaluations conducted. Both benefit measures were specific to the intervention under study. It is likely that they would be difficult to compare with the benefits of other health care interventions. The approach used to assign a monetary value to reassurance was based on the willingness to pay method, which is a commonly used instrument within the cost-benefit framework.

**Validity of estimate of costs**

The authors stated explicitly which perspective was adopted in the economic analysis. It appears that all the relevant categories of costs have been included in the study. A breakdown of the cost items was provided. However, details of the unit costs and quantities of resources used were not reported, therefore limiting the possibility of replicating the study in other settings. The source of the cost data was not reported. The price year was not provided and this would make reflation exercises in other settings difficult. The cost estimates were specific to the study setting and no sensitivity analyses were performed.

**Other issues**

The authors did not compare their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not performed, which limits the external validity of the analysis. The authors did not point out any potential limitations of their analysis.

**Implications of the study**

The study results suggested that lumbar spine radiography might be cost-effective only under specific conditions. The authors suggested that the patients should be educated about the usefulness of radiography in patients with low-back pain.

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