

Radiography for low back pain: a randomised controlled trial and observational study in primary care

Sally Kerry, Sean Hilton, Derek Dundas, Elizabeth Rink and Pippa Oakeshott

SUMMARY

Background: Lumbar spine radiography has limited use in diagnosing the cause of acute low back pain. Consensus-based guidelines recommend that lumbar spine x-rays are not used routinely. However, there have been no studies of the effect of referral for radiography at first presentation with low back pain in primary care.

Aim: To compare short and long-term physical, social, and psychiatric outcomes for patients with low back pain who are referred or not referred for lumbar spine x-ray at first presentation in general practice.

Design of study: A randomised unblinded controlled trial with an observational arm to enable comparisons to be made with patients not recruited to the trial.

Setting: Ninety-four general practices in south London and the South Thames region.

Method: Patients consulting their general practitioner (GP) with low back pain at first presentation were recruited to a randomised controlled trial (RCT) or to an observational group. Patients in the trial were randomly allocated to immediate referral for x-ray or to no referral. All patients were asked to complete questionnaires initially, and then at six weeks and one year after recruitment.

Results: Six hundred and fifty-nine patients were recruited over 26 months: 153 to the randomised trial and 506 to the observational arm. In the RCT, referral for x-ray had no effect on physical functioning, pain or disability, but was associated with a small improvement in psychological wellbeing at six weeks and one year. These findings were supported by the observational study in which there were no differences between the groups in physical outcomes after adjusting for length of episode at presentation; however, those referred for x-ray had lower depression scores.

Conclusions: Referral for lumbar spine radiography for first presentation of low back pain in primary care is not associated with improved physical functioning, pain or disability. The possibility of minor psychological improvement should be balanced against the high radiation dose involved.

Keywords: low back pain; radiography; randomised controlled trials; observation.

S Kerry, MSc, senior lecturer in medical statistics; S Hilton, MD, professor of general practice; D Dundas, FRCR, consultant radiologist; E Rink, MPhil, lecturer in primary health care sciences; P Oakeshott, MD, senior lecturer in general practice, Department of General Practice and Primary Care, St George's Hospital Medical School, London.

Address for correspondence

Mrs S Kerry, Department of General Practice and Primary Care, St George's Hospital Medical School, Cranmer Terrace, London SW17 0RE. E-mail: sgjdg2@sghms.ac.uk

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Introduction

MOST patients consulting their general practitioner (GP) with low back pain will improve within a few weeks,¹ although a minority will develop chronic back pain with continued disability. In rare cases there may be underlying malignancy or neurological deficit which needs to be identified.² Lumbar spine radiography is the most common investigation requested by GPs.³ However, it has limited use in diagnosing causes of acute back pain and involves a radiation dose 150 times that of a chest x-ray. The Royal College of Radiologists' guidelines recommend that unless pain is persistent, progressive, or there are neurological signs, there should be a delay of six to eight weeks before x-ray.⁴ However, these guidelines are consensus, not evidence-based and patient anxiety has been cited as a reason for not adhering to the guidelines.⁵⁻⁶ A small trial of radiography for low back pain carried out in the United States over 10 years ago⁷ found that referral for x-ray reinforced patients' belief in its usefulness but did not improve symptom resolution or disability. However, in the United Kingdom (UK) there have been no rigorous evaluations of the effect of referral for lumbar spine x-ray in patients at initial presentation with low back pain in primary care.⁸ The aims of this study were to compare short and long-term physical, social, and psychiatric outcomes for patients with low back pain who were or were not referred for lumbar spine x-ray at first presentation in general practice.

Method

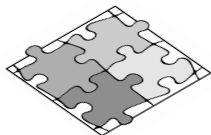
All 303 general practices in four Family Health Service Authority areas were approached. In the 94 practices which agreed to take part in the study, GPs were asked to recruit all patients aged between 16 and 64 years of age who consulted with low back pain to a randomised controlled trial (RCT) of referral for lumbar spine radiography. The patient information sheet for the trial explained that the benefits of radiography at first presentation were uncertain. Randomisation was at the time of the consultation and was carried out by opening a sealed opaque envelope. Alternatively, doctors could recruit patients not suitable or unwilling to be randomised to the observational study. The decision as to whether randomisation was appropriate was left to the individual doctors. They were all informed of the Royal College of Radiologists' (RCR) guidelines, and that these were not entirely evidence-based. To reduce any Hawthorne effect, the information sheet for the observational study did not mention radiography. Patients who had consulted with low back pain in the previous four weeks, who were pregnant, or who were suffering from influenza-like illness, were excluded.

HOW THIS FITS IN*What do we know?*

Current guidelines suggest that radiography is not routinely indicated in simple low back pain. However, lumbar spine radiography may be associated with improved patient satisfaction, and patient anxiety has been cited as a reason for not adhering to the guidelines.

What does this paper add?

Referral for radiography at first presentation with low back pain in general practice had no effect on physical function, pain or disability, but was associated with a small improvement in psychological wellbeing at six weeks and one year. In the absence of indications of serious spinal disease, lumbar spine radiography is not appropriate for first presentation of low back pain in primary care.



ed. Informed consent and ethical approval were obtained.

All patients were asked to complete a questionnaire at the time of recruitment, at six weeks, and again after one year. The questionnaires included the back-pain specific Roland and Morris disability scale,⁹ the Hospital Anxiety and Depression Scale (HADS),¹⁰ and the short form health survey SF-36¹¹ (in which a high score implies better quality of life). These questionnaires were chosen as they had been validated and could be completed independently by the patient. Information on the number of consultations and referrals, prescriptions, certified time off work, previous history, and radiology reports, was obtained from a search of GP-held records one year after recruitment.

Steps taken to enhance recruitment included ensuring that the recruitment procedure and inclusion criteria were as simple as possible, and not asking GPs to undertake any extra examination of the patient. In addition, when the first patient from a particular GP was recruited to the randomised trial, the GP was contacted to verify that the correct procedure had been followed. Questionnaire administration and follow-up were the responsibility of the research team. Practices also received regular newsletters and telephone calls about the study and an honorarium of £10 per patient recruited.

Intervention

Patients randomised to x-ray were referred on that date to their local x-ray department. Patients in the control group could be referred for x-ray at a later consultation if the doctor thought it appropriate.

Statistical analysis

Only patients responding to both the initial and at least one follow-up questionnaire were included in the final analysis. Student's *t*-tests were used to compare morbidity and quality of life indices between the intervention and control groups. Regression analysis was used to adjust for age, sex, and length of episode of low back pain (greater or less than eight weeks) at recruitment, using the bootstrap method.¹² This method was used because outcomes were not normally distributed. Length of episode was included as it is related to prognosis¹ and we wanted to examine the effect of

radiological referral on outcome independent of prognosis of low back pain. Odds ratios were used to compare consultations, referrals, and satisfaction between groups referred or not referred for radiography, and logistic regression used to adjust for age, sex, and length of episode.

A previous study had shown that 40% of patients with low back pain were still consulting after two weeks.¹³ The intended sample size of 150 in each group would have detected a fall to 25% still consulting in the referred group with 80% power and 5% significance. It was estimated that this could be achieved by 100 doctors recruiting for six months.¹⁴

Results**Participants**

Between January 1996 and March 1998, 138 GPs from 94 practices recruited 659 patients (Figure 1). Of these, 153 (23%) patients were recruited to the RCT and 506 (77%) to the observational study. The response rate to the questionnaire was 87% for the initial one, 73% at six weeks, and 67% at one year. Follow-up from patients' records at one year was 94%. Full details of all results are in the *Health Technology Assessment* report.¹⁴

Initial questionnaire (Tables 1 and 2)

RCT. Patients referred for x-ray were similar to those not referred in terms of pain score, past history of back pain, Roland Morris disability score, and HADS anxiety depression scores.

Observational study. Patients referred for x-ray were 3.5 years older than those not referred, and were more likely to have had back pain for more than eight weeks (51% versus 30%), to have previously consulted for back pain (35% versus 23%), and to have worse (lower) physical role scores, (implying more limitation of normal activities) with a mean score difference of 15 (6 to 25).

Outcome at six weeks and one year (Table 3)

RCT. There were no differences between the groups in physical functioning, pain or disability. However, at six weeks, patients who had been referred for x-ray tended to score better on the psychological measures, with a difference of 9 (3 to 15) points on the mental health scale and 8 (0 to 15) points on the vitality scales of the SF-36. After one year, the only difference was a better mental health score in patients referred for x-ray, with a mean score difference of 7 (0 to 14).

Observational study. Compared with patients who were not x-rayed, patients referred for x-ray had more pain at six weeks and one year and more disability at one year. After adjusting for duration of back pain at presentation, these differences disappeared. However, patients who had been referred for radiography had lower adjusted depression scores at both six weeks and one year.

Patient expectation, satisfaction, repeat consultations and referrals (Table 4)

RCT. There were no differences between the groups in expectation, satisfaction, or repeat consultations or referrals

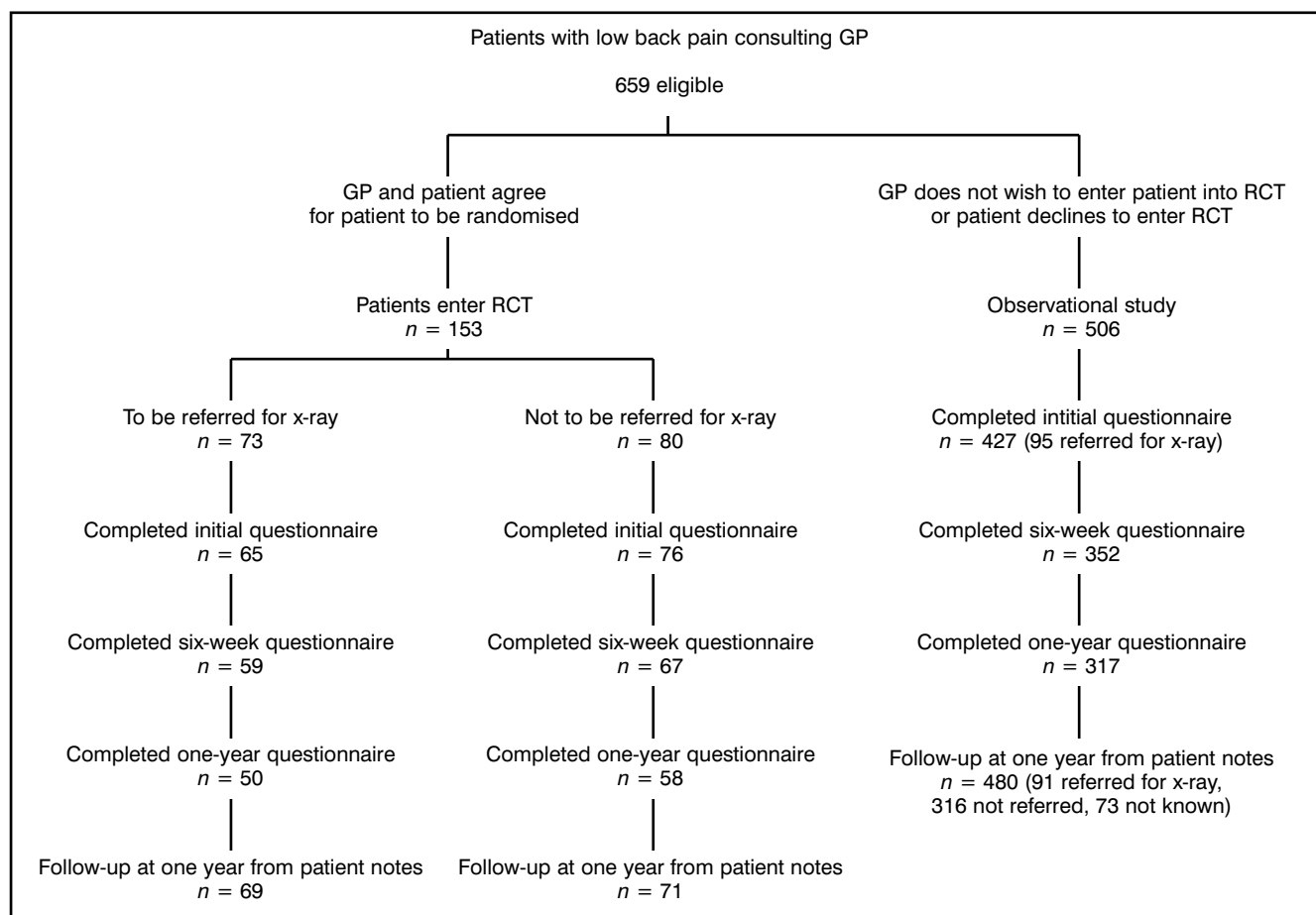


Figure 1. Flow of patients through the study.

Table 1. Social variables, symptoms, pain, and previous consultations in 568 patients with low back pain who completed the initial questionnaire.

| | Randomised patients | | Observational patients | |
|---|---|---|--|---|
| | Not referred for x-ray Total = 76 n (%) | Referred for x-ray Total = 65 n (%) | Not referred for x-ray Total = 332 n (%) | Referred for x-ray Total = 95 n (%) |
| Patient characteristics | | | | |
| Mean age (SD) ^a | 44.0 (12.1) | 44.2 (12.1) | 41.1 (11.8) | 44.6 (10.0) ^c |
| Female sex | 44 (58) | 26 (40) ^c | 177 (53) | 54 (57) |
| In work | 49 (64) | 50 (77) | 255 (77) | 64 (67) |
| Social class I and II | 16 (25) | 19 (33) | 93 (34) | 21 (28) |
| Pain score on day of questionnaire | | | | |
| Very bad or unbearable pain | 15 (20) | 14 (22) | 73 (23) | 20 (22) |
| Past history of three or more episodes of back pain | 39 (57) | 32 (54) | 153 (49) | 47 (55) |
| Length of episode of low back pain^b | | | | |
| Less than one week | 22 (30) | 14 (22) ^c | 105 (33) | 15 (17) ^d |
| One to less than 8 weeks | 36 (49) | 27 (42) | 119 (37) | 29 (32) |
| Eight weeks to less than 6 months | 4 (5) | 3 (5) | 34 (11) | 18 (20) |
| Six months and over | 12 (16) | 20 (31) | 62 (19) | 28 (31) |
| Consultation and x-ray history and referrals | | | | |
| Mean consultations in past year (SD) | 4.8 (4.5) | 3.6 (3.3) | 4.0 (3.9) | 3.9 (4.1) |
| Consulted with back pain in previous year | 17 (25) | 16 (26) | 73 (23) | 32 (35) ^c |
| Lumbar spine x-ray in past 5 years | 10 (15) | 5 (8) | 29 (9) | 4 (4) |

There are 100 patients with missing values for social class, and 34 patients with missing values for consultations. Statistical tests compare referred and not referred patients, χ^2 -test except. ^at-test. ^b χ^2 -test for trend (length of episode). ^c $P < 0.05$. ^d $P < 0.001$.

Table 2. Initial scores on short form health survey SF-36, Hospital Anxiety and Depression Scale.

| | Randomised patients | | | | Observational patients | | | |
|---------------------------------------|-------------------------------------|---------------------------------|----------------------------|------------------------------|--------------------------------------|---------------------------------|---------------------------|------------------------------|
| | Mean (SD) not referred (total = 76) | Mean (SD) referred (total = 65) | Difference (95% CI) | Adjusted difference (95% CI) | Mean (SD) not referred (total = 332) | Mean (SD) referred (total = 95) | Difference (95% CI) | Adjusted difference (95% CI) |
| SF-36 item | | | | | | | | |
| Physical functioning | 57 (28) | 66 (24) | -9 (-17 to 0) ^a | -9 (-17 to 0) | 63 (27) | 60 (24) | 3 (-3 to 9) | 0 (-6 to 6) |
| Physical role | 34 (40) | 40 (43) | -6 (-20 to 9) | -3 (-17 to 13) | 46 (43) | 31 (36) | 15 (6 to 25) ^b | 10 (0 to 19) |
| Bodily pain | 36 (20) | 38 (21) | -2 (-9 to 4) | -3 (-10 to 5) | 45 (26) | 41 (22) | 4 (-2 to 10) | 2 (-4 to 8) |
| General health | 65 (23) | 68 (21) | -3 (-11 to 5) | -5 (-3 to 13) | 70 (20) | 71 (17) | -1 (-6 to 4) | -4 (-8 to 0) |
| Vitality | 45 (23) | 48 (21) | -3 (-10 to 4) | -1 (-8 to 7) | 51 (22) | 47 (19) | 4 (-1 to 9) | 0 (-5 to 6) |
| Social functioning | 63 (25) | 66 (26) | -3 (-11 to 5) | -2 (-11 to 8) | 67 (27) | 63 (25) | 4 (-3 to 10) | 0 (-6 to 6) |
| Emotional role | 64 (42) | 66 (43) | -2 (-16 to 13) | -2(-18 to 12) | 71 (41) | 64 (45) | 7 (-3 to 16) | -2 (-12 to 10) |
| Mental health | 66 (17) | 68 (18) | -2 (-8 to 4) | -1(-8 to 5) | 69 (19) | 70 (17) | -1 (-5 to 4) | -3 (-8 to 1) |
| Hospital Anxiety and Depression Scale | | | | | | | | |
| Depression score | 5.4 (3.9) | 5.0 (3.3) | 0.3 (-0.9 to 1.6) | 0.4 (-0.9 to 1.7) | 5.0 (3.9) | 4.8 (3.2) | 0.3 (-0.6 to 1.1) | 0.7 (-0.2 to 1.5) |
| Anxiety score | 8.2 (4.6) | 7.4 (4.6) | 0.8 (-0.8 to 2.4) | 0.4 (-1.2 to 2.1) | 7.1 (4.3) | 7.5 (4.0) | -0.4 (-1.4 to 0.6) | -0.1 (-1.1 to 0.8) |
| Roland and Morris | | | | | | | | |
| Disability score | 10.9 (5.3) | 10.2 (5.5) | 0.7 (-1.1 to 2.5) | 0.6 (-1.2 to 2.4) | 10.8 (5.4) | 10.9 (5.5) | -0.1 (-1.4 to 1.2) | -0.3 (-1.6 to 1.1) |

Unadjusted difference between referred and not referred patients and adjusted for age, sex, and length of episode at presentation. There are differing numbers of missing values (41 patients in total for any variable). ^aP<0.05. ^bP<0.01.

Table 3. Six-week and one-year scores on short form health survey SF-36, Hospital Anxiety and Depression Scale.

| | Randomised patients | | | | Observational patients | | | |
|---------------------------------------|-------------------------------------|--------------------|-----------------------------|------------------------------|------------------------|--------------------|----------------------------------|-------------------------------|
| | Mean (SE) ^a not referred | Mean (SE) referred | Difference (95% CI) | Adjusted difference (95% CI) | Mean (SE) not referred | Mean (SE) referred | Difference (95% CI) | Adjusted difference (95% CI) |
| Six weeks (n) | | | | | | | | |
| SF-36 | | | | | | | | |
| Physical functioning | 67 | 59 | | | 276 | 76 | | |
| Physical functioning | 65 (3) | 67 (3) | -2 (-12 to 7) | -2 (-11 to 7) | 71 (1) | 63 (3) | 7 (1 to 14) ^b | 1(-5 to 8) |
| Physical role | 45 (5) | 41 (6) | 4 (-12 to 20) | 7 (-9 to 22) | 54 (3) | 46 (5) | 8 (-3 to 20) | 0 (-12 to 12) |
| Bodily pain | 49 (3) | 49 (3) | -1 (-10 to 8) | -1 (-10 to 7) | 56 (2) | 49 (3) | 7 (0 to 14) ^b | 1 (-5 to 7) |
| General health | 67 (3) | 69 (3) | -2 (-10 to 6) | -3 (-10 to 5) | 68 (1) | 69 (2) | -1 (-6 to 4) | -5 (-10 to 0) |
| Vitality | 46 (3) | 54 (2) | -8 (-15 to 0) ^b | -7 (-15 to 1) | 52 (1) | 54 (2) | -2 (-7 to 4) | -6 (-11 to 0) ^b |
| Social functioning | 67 (4) | 72 (3) | -5 (-15 to 4) | -4 (-13 to 6) | 74 (2) | 69 (3) | 5 (-2 to 12) | 1 (-6 to 7) |
| Emotional role | 65 (5) | 75 (5) | -10 (-24 to 5) | -8 (-22 to 6) | 67 (3) | 70 (5) | -2 (-14 to 9) | -7 (-19 to 5) |
| Mental health | 65 (3) | 74 (3) | -9 (-15 to -3) ^c | -8 (-14 to -1) ^b | 68 (1) | 71 (2) | -4 (-9 to 1) | -6 (-11 to -1) ^b |
| Hospital Anxiety and Depression Scale | | | | | | | | |
| Depression score | 5.1 (0.5) | 4.7 (0.5) | 0.5 (-0.9 to 1.8) | 0.6 (-0.9 to 2.1) | 4.5 (0.3) | 4.2 (0.4) | 0.2 (-0.8 to 1.2) | 1.0 (0.1 to 2.0) ^a |
| Anxiety score | 7.7 (0.6) | 6.8 (0.5) | 0.9 (-0.7 to 2.5) | 0.5 (-0.9 to 1.8) | 7.3 (0.3) | 7.2 (0.4) | 0.2 (-1.0 to 1.3) | 0.8 (-0.3 to 2.0) |
| Roland and Morris | | | | | | | | |
| Disability score | 6.9 (0.8) | 5.9 (0.7) | 1.0 (-1.1 to 3.1) | 0.7 (-1.2 to 2.8) | 5.4 (0.3) | 6.7 (0.6) | -1.3 (-2.7 to 0.0) | -0.2 (-1.5 to 1.2) |
| One year (n) | | | | | | | | |
| SF-36 | | | | | | | | |
| Physical functioning | 58 | 50 | | | 254 | 63 | | |
| Physical functioning | 73 (3) | 75 (3) | -2 (-10 to 7) | -4 (-12 to 4) | 74 (2) | 70 (3) | 4 (-2 to 11) | -3 (-9 to 3) |
| Physical role | 67 (5) | 66 (6) | 0 (-16 to 16) | -5 (-20 to 11) | 69 (3) | 61 (5) | 8 (-3 to 19) | 2 (-10 to 14) |
| Bodily pain | 63 (3) | 63 (4) | -1 (-11 to 9) | -4 (-14 to 6) | 65 (2) | 58 (3) | 7 (0 to 14) ^b | 2 (-5 to 8) |
| General health | 67 (3) | 68 (3) | -1 (-10 to 7) | -4 (-12 to 5) | 68 (1) | 67 (3) | 1 (-5 to 7) | -3 (-8 to 3) |
| Vitality | 52 (3) | 57 (3) | -4 (-13 to 4) | -6 (-14 to 3) | 56 (1) | 53 (3) | 3 (-3 to 9) | -1 (-7 to 5) |
| Social functioning | 79 (4) | 81 (4) | -2 (-12 to 8) | -5 (-14 to 5) | 81 (1) | 77 (3) | 5 (-2 to 12) | 0 (-7 to 7) |
| Emotional role | 78 (5) | 82 (5) | -4 (-18 to 10) | -7 (-20 to 7) | 78 (2) | 79 (5) | -1 (-11 to 10) | -9 (-18 to 0) |
| Mental health | 70 (2) | 77 (2) | -7 (-14 to 0) ^b | -8 (-15 to -2) ^b | 71 (1) | 71 (2) | 0 (-5 to 5) | -3 (-8 to 2) |
| Hospital Anxiety and Depression Scale | | | | | | | | |
| Depression score | 4.1 (0.5) | 3.8 (0.5) | 0.3 (-1.1 to 1.7) | 0.7 (-0.7 to 2.0) | 4.1 (0.2) | 3.7 (0.4) | 0.3 (-0.7 to 1.4) | 1.1 (0.1 to 2.0) ^b |
| Anxiety score | 6.7 (0.6) | 6.3 (0.6) | 0.4 (-1.4 to 2.1) | 0.6 (-1.2 to 2.4) | 6.5 (0.3) | 6.3 (0.5) | 0.2 (-0.9 to 1.4) | 1.0 (-0.2 to 2.2) |
| Roland and Morris | | | | | | | | |
| Disability score | 4.3 (0.7) | 4.5 (0.8) | -0.2 (-2.2 to 1.8) | -0.3 (-1.6 to 2.2) | 4.2 (0.3) | 5.6 (0.6) | -1.4 (-2.8 to -0.1) ^b | -0.3 (-1.8 to 1.0) |

Unadjusted difference between referred and not referred patients and adjusted for age, sex and length of episode at presentation. ^aSE = standard error. Some patients have missing data for some variables (39 patients). ^bP<0.05. ^cP<0.01.

for back pain.

Observational study. Patients referred for x-ray were 15 times more likely than those not referred to have expected referral. They were also more satisfied, more likely to reconsult for back pain, and more likely to be referred to a physiotherapist or other health professional.

Compliance with intervention

There were four patients, one in the group not referred and three in the x-ray group, whose notes confirmed non-compliance with the randomisation allocation. Analysis was by group to which the patient was randomised.

Discussion

Principal findings

In the RCT, referral for x-ray had no effect on physical functioning, pain, disability, further consultations or referrals, but was associated with a small improvement in psychological measures at six weeks and one year. These findings were supported by the observational study, in which there were no differences between the groups in physical outcomes after adjusting for length of episode at presentation, but th

Strengths and weaknesses of the study

This is the first UK primary care-based trial of referral for radiology at initial presentation of low back pain. One of its main strengths is that patients were recruited at the time of a normal, everyday consultation in a general practice surgery, rather than retrospectively using medical records.¹⁵ Secondly, follow-up at one year was over 90%. Thirdly, the benefit of a partly randomised preference trial such as this is that patients randomly allocated to the intervention can be compared with patients with a preference in the observational arm. By not excluding patients, and thus increasing enrolment of eligible patients, these studies provide powerful external validation for the results of RCTs and may be more generalisable to 'real world' populations. Finally, analysis of computer records at three study practices showed that 15 patients with low back pain recruited to the study were similar to 69 not recruited in terms of consultation history, age and sex.¹⁴

The main weakness of the study is that only 23% of patients recruited were randomised and only 51% of our recruitment target was achieved, thus reducing the power of the study. However, this sample size still had a power of 78% to detect a 2.5 point improvement in the Roland Morris score, a change considered important by the Back Pain Working Party. Persuading busy GPs to recruit and randomise even 153 patients with low back pain during a rou-

Table 4. Patient expectation and satisfaction, repeat consultations and referrals to physiotherapists and other health professionals.

| | Randomised patients | | | | Observational arm | | | |
|--|-------------------------------------|---------------------------------|------------------------|--|--------------------------------------|---------------------------------|----------------------------------|--|
| | Not referred n (%) Total = 76 | Referred n (%) Total = 65 | Odds ratio (95% CI) | Adjusted odds ratio ^a (95% CI) | Not referred n (%) Total = 332 | Referred n (%) Total = 95 | Odds ratio (95% CI) | Adjusted odds ratio ^a (95% CI) |
| Patients' expectations of their GPs | | | | | | | | |
| Advice | 45 (59) | 34 (52) | 0.76 (0.39 to 1.5) | 0.80 (0.39 to 1.6) | 209 (63) | 50 (53) | 0.65 (0.41 to 1.0) | 0.70 (0.43 to 1.2) |
| Prescription | 43 (57) | 29 (45) | 0.62 (0.32 to 1.2) | 0.59 (0.29 to 1.2) | 164 (49) | 37 (39) | 0.65 (0.41 to 1.0) | 0.83 (0.51 to 1.4) |
| Sickness certificate | 9 (12) | 5 (8) | 0.62 (0.20 to 2.0) | 0.48 (0.14 to 1.7) | 50 (15) | 9 (9) | 0.59 (0.28 to 1.2) | 0.60 (0.26 to 1.3) |
| X-ray | 14 (18) | 17 (26) | 1.6 (0.70 to 3.5) | 1.5 (0.66 to 3.6) | 35 (11) | 61 (64) ^g | 15.2 (8.8 to 26.3) ^g | 13.0 (7.4 to 23.0) ^g |
| Referral to specialist | 22 (29) | 28 (43) | 1.9 (0.92 to 3.7) | 1.9 (0.91 to 3.9) | 105 (32) | 40 (42) | 1.6 (0.98 to 2.5) | 1.5 (0.93 to 2.5) |
| Satisfaction with initial consultation^b | | | | | | | | |
| Very satisfied | 37 (49) | 38 (59) | 1.0 | 1.0 | 150 (46) | 59 (63) ^g | 1.0 | 1.0 |
| Satisfied | 27 (36) | 21 (33) | 0.76 (0.37 to 1.6) | 0.87 (0.40 to 1.9) | 130 (40) | 33 (35) | 0.64 (0.40 to 1.0) | 0.61 (0.37 to 1.0) |
| Indifferent or dissatisfied | 11 (14) | 5 (8) | 0.44 (0.14 to 1.4) | 0.41 (0.12 to 1.3) | 45 (14) | 2 (2) | 0.11 (0.03 to 0.48) ^f | 0.11 (0.03 to 0.50) ^f |
| Satisfaction at six weeks^c | | | | | | | | |
| Very satisfied | 19 (28) | 19 (33) | 1.0 | 1.0 | 64 (23) | 28 (37) ^e | 1.0 | 1.0 |
| Satisfied | 28 (42) | 26 (45) | 0.93 (0.40 to 2.1) | 0.89 (0.37 to 2.1) | 139 (51) | 32 (43) | 0.53 (0.29 to 0.95) ^e | 0.40 (0.21 to 0.77) ^f |
| Indifferent or dissatisfied | 20 (30) | 13 (22) | 0.80 (0.39 to 1.6) | 0.54 (0.19 to 1.5) | 72 (26) | 15 (20) | 0.48 (0.23 to 0.97) ^e | 0.33 (0.15 to 0.73) ^f |
| Consulted subsequently for back pain^d | | | | | | | | |
| Within 6 weeks | 26 (38) | 21 (34) | 0.84 (0.41 to 1.7) | 0.81 (0.37 to 1.8) | 92 (29) | 38 (42) ^e | 1.7 (1.1 to 2.8) ^e | 2.1 (1.2 to 3.5) ^f |
| Six weeks to 1 year | 28 (41) | 21 (34) | 0.75 (0.37 to 1.5) | 0.67 (0.31 to 1.4) | 89 (28) | 40 (44) ^f | 2.0 (1.2 to 3.2) ^f | 1.6 (0.95 to 2.7) |
| Referrals to physiotherapist or other health professional^d | | | | | | | | |
| At recruitment | 13 (19) | 12 (20) | 1.1 (0.50 to 2.6) | 1.4 (0.55 to 3.6) | 49 (16) | 24 (26) | 1.9 (1.1 to 3.4) ^e | 1.8 (1.0 to 3.2) |
| Within 6 weeks | 19 (28) | 18 (30) | 1.1 (0.50 to 2.3) | 1.5 (0.66 to 3.4) | 73 (23) | 40 (44) ^g | 2.6 (1.6 to 4.2) ^g | 2.4 (1.4 to 3.9) ^f |
| Six weeks to 1 year | 32 (47) | 27 (44) | 0.89 (0.45 to 1.8) | 1.1 (0.52 to 2.3) | 117 (37) | 52 (57) ^g | 2.3 (1.4 to 3.6) ^g | 1.9 (1.2 to 3.2) ^g |

^aAdjusted for age, sex, and length of episode. ^bn = 139 for trial and 419 for observational arm. ^cn = 125 for trial and 350 for observational arm. ^dn = 129 for trial and 405 for observational arm. ^eP < 0.05. ^fP < 0.01. ^gP < 0.001.

tine consultation is an achievement.

Despite lack of evidence, some clinicians held strong views about the appropriateness of x-rays. Many of the 65 doctors who only recruited patients to the observational arm said they were unwilling to recruit to a randomised study.¹⁴ This situation has been described by Black as one of 'collective equipoise' without 'individual equipoise' and may make experimentation impossible.¹⁶ In the current study we did randomise patients, but not as many as we had intended. The problems of encouraging and reminding GPs to recruit patients to such trials have been widely discussed.¹⁷

A second limitation is the small baseline difference between the two groups in the randomised trial. Patients referred for x-ray had been in pain for longer, a factor related to poor prognosis. However, adjusting for baseline differences did not affect the main findings. A third limitation is potential follow-up bias. It is possible that some of the beneficial effect of referral for x-ray on mental health scores is owing to bias of the patients who responded to the follow-up questionnaires. However, the mean mental health scores of patients responding to the initial questionnaire were the same, whether or not they responded to the follow-up questionnaires.¹⁴ Finally, the patient information sheet for the trial may have influenced the results by raising new doubts in patients' minds about the benefits of radiography in low back pain and the risks of unnecessary radiation.

Another consideration is the risk of missing serious pathology. In addition to the RCR guidelines⁴, the Royal College of General Practitioners' (RCGP) guidelines on management of acute low back pain¹⁸ recommend prompt referral for presentation under the age of 20 or over the age of 55 years, non-mechanical pain, thoracic pain, past history of carcinoma, steroids, HIV, being unwell, weight loss, widespread neurology, or structural deformity. Sphincter or gait disturbance or saddle anaesthesia warrant immediate referral. Otherwise, the RCR guidelines recommend that patients wait six to eight weeks before x-ray. However, as in Croft's study,¹⁹ we found that although some patients reattended at between two and four weeks, few reconsulted after six weeks, even though their symptoms did not improve.¹⁴ It is vital to ask patients to come back if they are not getting better. Just as issuing delayed or post-dated prescriptions has provided a useful alternative in the management of upper respiratory tract infections,²⁰ an opportunity for reassessment may be a useful alternative to immediate referral for x-ray.

Comparison with other studies

There has been only one other UK trial of lumbar spine radiography in primary care patients with low back pain.¹⁵ This study was very different from the current one, as it only included patients with low back pain for at least six weeks' duration (median = 10 weeks). In addition, patients were not recruited at the time of consultation, and those who had already been referred for radiography before six weeks were excluded. However, their main findings are in line with ours: referral for radiography was not associated with improved patient functioning, severity of pain, or overall health status.

Conclusions

The results of this study are consistent with existing guide-

lines: early x-ray for low back pain is not routinely recommended, although it might be considered if patient anxiety is a major feature. Patient information and education need to reinforce the message that the benefit from early x-ray is negligible and that the radiation dose from lumbar spine radiography is high. However, patients must be advised to reconsult if symptoms do not resolve. The most appropriate follow-up for low back pain, including timing and nature of diagnostic imaging, needs further research.

References

1. Roland MO, Morrell DC, Morris RW. Can general practitioners predict the outcome of episodes of back pain? *BMJ* 1983; **286**: 523-525.
2. Clinical Standards Advisory Group. *Report on back pain*. London: HMSO, 1994.
3. Office of Population Censuses and Surveys. Mason V. *The prevalence of back pain in Great Britain*. London: HMSO, 1993.
4. Royal College of Radiologists. *Making the best use of a department of clinical radiology: guidelines for doctors*. 3rd edition. London: Royal College of Radiologists, 1995.
5. Owen JP, Rutt G, Keir MJ, *et al*. Survey of general practitioners' opinions on the role of radiology in patients with low back pain. *BJGP* 1990; **40**: 98-101.
6. Kerry S, Oakeshott P, Dundas DD, and Williams J. Influence of postal distribution of the Royal College of Radiologists' guidelines, together with feedback on radiological referral rates, on X-ray referrals from general practice: a randomised controlled trial. *Fam Pract* 2000; **17**: 46-52.
7. Deyo RA, Diehl AK, Rosenthal M. Reducing roentgenography use. Can patient expectations be altered? *Arch Intern Med* 1987; **147**: 141-145.
8. Little P, Cantrell T, Roberts L, *et al*. Why do GPs perform investigations? The medical and social agendas in arranging back X-rays. *Fam Pract* 1998; **15**: 264-265.
9. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low back pain. *Spine* 1983; **8**: 141-144.
10. Zigmond A, and Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scand* 1983; **67**: 361-370.
11. Ware JE, and Sherbourne CD. The MOS 36-Item Short Form Health Survey: conceptual framework and item selection. *Medical Care* 1992; **30**: 473-483.
12. Efron B, Tibshirani RJ. *An introduction to the bootstrap*. New York: Chapman Hall, 1993.
13. Roland M, Dixon M. Randomized controlled trial of an educational booklet for patients presenting with back pain in general practice. *J R Coll Gen Pract* 1989; **39**: 244-246.
14. Kerry S, Hilton S, Dundas D, *et al*. Routine referral for X-ray for patients presenting with low back pain: is the outcome for patients influenced by GPs' referral for plain radiography? *Health Technol Assess* 2000; **4(20)**: i-iv, 1-119.
15. Kendrick D, Fielding K, Bentley E, *et al*. Radiography of the lumbar spine in primary care patients with low back pain: randomised controlled trial. *BMJ* 2001; **322**: 400-405.
16. Black N. Why we need observational studies to evaluate the effectiveness of health care. *BMJ* 1996; **312**: 1215-1218.
17. Pringle M, Churchill R. Randomised controlled trials in general practice. *BMJ* 1995; **311**: 1382-1383.
18. Royal College of General Practitioners. *Clinical guidelines for the management of acute low back pain*. London: Royal College of General Practitioners, 1996.
19. Croft PR, Macfarlane GJ, Papageorgiou AC, *et al*. Outcome of low back pain in general practice: a prospective study. *BMJ* 1998; **316**: 1356-1359.
20. Holmes WF, Macfarlane JT, Macfarlane RM, Lewis S. The influence of antibiotics and other factors on the reconsultation for acute lower respiratory tract illness in primary care. *BJGP* 1997; **47**: 815-918.

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