

Stratified versus usual care for the management of primary care patients with sciatica: the SCOPiC RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The SCOPiC RCT

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Scientific summary

Background

Sciatica is a commonly used term to describe symptoms of pain radiating from the lower back to the leg(s), often accompanied by pins and needles, numbness or leg muscle weakness. A prolapsed disc or spinal stenosis causing compression of lumbar spinal nerve root(s) are the most common causes of sciatica. Compared with lower-back pain alone, sciatica has a more substantial impact on patients and significant health-care, social and economic burdens. The UK annual costs for sciatica have been estimated as £268M in direct medical costs, plus £1.9B in indirect costs.

In the UK, most patients with sciatica are assessed and managed in primary care. Usual primary care practice takes a stepped approach, starting with conservative interventions such as advice and education, medications and physiotherapy, with those failing to improve eventually being offered imaging tests and specialist assessment. In the absence of a systematic way to identify patients who need to be referred to specialists for consideration of more invasive treatments, there is considerable variation in practice and the current stepped-care approach means that most patients have to 'fail' previous interventions before being stepped up to the next intervention. This may cause delays in referral to spinal specialists for patients who should be considered for injections or surgery, as well as causing frustration for patients and spinal specialists.

More systematic identification of subgroups of sciatica patients for matched care pathways (stratified care) may lead to patients receiving the right treatment at the right time for them, and thus improve symptoms and outcomes. However, it is challenging for clinicians to identify, early in the presentation, those patients who are likely to do well with conservative management in primary care and those who may need early, fast-track referral to spinal specialists.

A model of stratified care has previously been shown to be both clinically effective and cost-effective in the primary care management of non-specific lower-back pain. That stratified care approach used a screening tool to identify patients' prognostic risk of persistent back pain-related disability to match patients to one of three treatments. An adapted stratified care algorithm was developed prior to the Sciatica Outcomes in Primary Care (SCOPiC) trial, specifically for primary care patients with sciatica. The algorithm combined prognostic criteria with clinical criteria associated with referral to spinal specialist services, to match patients with care pathways, including fast-track referral to specialists.

Objectives

The aim of the SCOPiC trial was to compare the clinical effectiveness and cost-effectiveness of the new stratified care approach for sciatica that combines information on risk of persistent disability with information about sciatica clinical severity, to allocate patients into one of three groups with matched care pathways, versus non-stratified, usual care. Linked qualitative interviews explored patients' and clinicians' views and experiences of the fast-track care pathway tested in the trial.

Methods

The SCOPiC trial was a two-parallel-group, multicentre, pragmatic randomised controlled trial with 1 : 1 allocation and an internal pilot phase. Patients were recruited from general practices in three areas: (1) North Staffordshire, (2) North Shropshire/Wales and (3) Cheshire. Eligible patients were aged

≥ 18 years, with a clinical diagnosis of sciatica symptoms (diagnostic confidence of ≥ 70%) of any severity and duration following clinical assessment in research clinics, with access to a mobile phone/landline, who were not receiving treatment or had received treatment in the previous 3 months for the same problem, were not pregnant and had no previous lumbar spine surgery. Patients with suspected serious spinal pathology (e.g. cauda equina compression), serious physical or mental comorbidities and those taking part, at the same time, in another research study about sciatica were excluded.

Potential participants were identified by electronic 'pop-up' prompts in general practice computer systems fired by appropriate diagnostic or symptom codes, or by weekly reviews of practice consultation records for those practices not using electronic 'pop-ups', with the list of potential participants screened by general practitioners prior to invitation to participate in the trial. A letter of invitation, including information about the SCOPiC trial research clinic and the research study, was posted to potentially eligible participants, inviting them to telephone an administrator to make an appointment at the SCOPiC trial research clinic to see a physiotherapist. Preliminary eligibility checks for the trial were carried out during the telephone call, and full eligibility screening and baseline assessment, including identifying each patient's sciatica group according to the stratification algorithm, were conducted at the research clinic by trial physiotherapists.

Eligible patients who gave written, informed consent were randomised by computer-generated code to either stratified care or usual care. Randomisation was carried out using a web-based randomisation service from Keele Clinical Trials Unit, and was stratified by centre and stratification group allocation (sciatica groups: 1, 2, 3). Different physiotherapists delivered treatment to participants in each trial arm to avoid contamination.

In the stratified care arm, the sciatica stratification algorithm was used to allocate patients to one of three groups: group 1 received brief advice, education and support in up to two physiotherapy sessions; group 2 received up to six physiotherapy sessions; and group 3 received a fast-track referral to an imaging and spinal specialist assessment. All usual care participants had a consultation with a physiotherapist. Their care was planned without the use of any stratification tool or algorithm; referrals for further physiotherapy or to other services could be made at the discretion of the assessing physiotherapist and in consultation with the patient.

The primary outcome was time to first resolution of sciatica symptoms, defined as 'completely recovered' or 'much better', measured on a six point ordinal scale and collected via text messages. Primary outcome data collection occurred weekly for the first 4 months for all participants, and then every 4 weeks between 4 and 12 months' follow-up, or until 'stable resolution' of symptoms (defined as 2 consecutive months' responses of 'completely recovered' or 'much better'). Secondary outcomes (at 4 and 12 months) included leg and back pain intensity, physical function, psychological status, time off work, work productivity, satisfaction with care, health-care use and health-related quality of life. Kaplan-Meier survival analysis estimated the time from randomisation until reporting of first resolution of sciatica symptoms. Cox regression analysis estimated the hazard ratio for the rate of symptoms resolution. The clinical effectiveness on secondary outcomes was analysed using intention to treat. Participants' health-care utilisation was described.

The economic evaluation comprised a within-trial analysis over 12 months. The economic analysis assessed cost consequences, including NHS and patient costs, and the costs of lost production. All costs were based on 2017 prices. The primary analysis was a cost-utility analysis of the incremental cost per quality-adjusted life-year gained between trial arms. Resource use and quality-of-life data (measured using the EuroQol-5 Dimensions, five-level version) were obtained from postal questionnaires, and mean costs and quality-adjusted life-years were calculated for each trial arm. Incremental cost-effectiveness ratios were estimated and cost-effectiveness acceptability curves constructed. The base-case analysis took the form of an intention-to-treat approach, using multiple imputation, performed from an NHS and

Personal Social Services perspective. Additional secondary analyses included alternative costing perspectives and cost analyses incorporating hospital record data from participating sites.

To determine, and understand, the acceptability of the fast-track pathway to patients in sciatica group 3 in the stratified care arm, and to the clinicians who were either directly involved in patient care in this pathway or would be if this were to become incorporated into current clinical management in the future, semistructured interviews were conducted with patients, general practitioners, spinal physiotherapy specialists from the spinal interface clinics and spinal surgeons. A purposeful sampling strategy was used to ensure diverse patient characteristics. Clinicians were sampled for variation across the different recruiting areas.

Results

From 42 general practices, 2719 adults with suspected sciatica were invited to contact the SCOPiC trial research team; 1269 attended a SCOPiC trial research clinic for full eligibility screening. Between May 2015 and July 2017, 476 patients were randomised (238 in each arm). The mean age was 52.1 years (standard deviation 14 years) and 55% were female (262/476). Overall, the stratification algorithm allocated 107 (22.5%) patients to group 1, 211 (44.3%) to group 2 and 158 (33.2%) to group 3. For the primary outcome, the overall response rate was 89.3% (stratified care, 88.3%; usual care, 90.3%). The follow-up rates of the 4- and 12-month questionnaires, overall and including minimal data collection, were 82.6% (stratified care, 80.7%; usual care, 84.5%) and 75.4% (stratified care, 74.4%, usual care, 76.5%), respectively. Baseline characteristics were similar in both trial arms. Non-responders to the 4- and 12-month questionnaires tended to be younger, living in significantly more deprived neighbourhoods and had slightly worse baseline health status than those who completed the questionnaires. At the point of randomisation, the stratified care algorithm for allocating patients to one of the three matched care pathways was followed in all but four cases (four patients in group 1 were not referred on to be offered one to two sessions of physiotherapy).

Median time to resolution of sciatica symptoms was 10 (95% confidence interval 6.4 to 13.6) and 12 (95% confidence interval 9.4 to 14.6) weeks for stratified care and usual care, respectively. This difference (median 2 weeks, in favour of stratified care) was not statistically significant (hazard ratio 1.14, 95% confidence interval 0.89 to 1.46; $p = 0.288$). Per-protocol and sensitivity analyses for secondary definitions of symptom resolution also showed no statistically significant differences between the trial arms. This was also the case for the complete-case analysis (those participants responding to all text messages sent). On average, up to 80% of participants in both arms reported some improvement ('completely recovered' or 'much better' or 'better') at some point from baseline. Prespecified subgroup analyses showed similar outcomes between trial arms, except for the group of participants clinically diagnosed with spinal stenosis, for whom stratified care seemed to lead to faster improvement (median 4 weeks) (hazard ratio 1.92, 95% confidence interval 1.01 to 3.65).

There were no significant between-arm differences in secondary outcomes; most participants in both arms improved over time on most outcomes. At 4 and 12 months, the mean difference (stratified care – usual care) in sciatica-related disability (measured using the Roland–Morris Disability Questionnaire) was 0.43 (95% confidence interval –0.69 to 1.54) and –0.53 (95% confidence interval –1.84 to 0.78), respectively. Most participants in both trial arms were satisfied with the care they received. There were no adverse events in either trial arm. Self-report and hospital record data showed that 22 participants receiving stratified care and 13 receiving usual care received spinal injections, and five receiving stratified care and eight receiving usual care had spinal surgery.

The mean costs recorded in each arm were £663.58 (standard deviation £737.14) for stratified care and £617.37 (standard deviation £935.50) for usual care. The mean quality-adjusted life-years associated with each arm were 0.6599 (standard deviation 0.1731) for stratified care and 0.6713

(standard deviation 0.1685) for usual care. The mean adjusted quality-adjusted life-year difference between the arms was -0.011 in favour of usual care. For both the quality-adjusted life-years and costs, the 95% confidence intervals overlapped zero, highlighting uncertainty in the estimate. In the primary base-case analysis, stratified care was not likely to be cost-effective, with only an 18% chance of being cost-effective at a threshold of £20,000 per quality-adjusted life-year gained. The net monetary benefit was $-\text{£}275$ if society's willingness to pay for a quality-adjusted life-year is valued at £20,000. Secondary analyses gave consistent results that stratified care was not likely to be a cost-effective option compared with usual care.

In the qualitative interviews, participants emphasised the overwhelming impact sciatic symptoms had on their life. The fast-track pathway of the stratified care model tested in this trial was felt to be acceptable to both patients and clinicians, particularly for providing reassurance for those with severe symptoms. However, it was evident that for patients who were potential candidates for injection and/or surgery, but had short durations of symptoms, both clinicians and patients preferred to try conservative management, thus giving time for symptoms to potentially improve before invasive interventions.

Conclusions

- The trial did not find convincing evidence that this model of stratified care led to faster improvement or better clinical results than usual care for patients with clinically diagnosed sciatica.
- Participants in the stratified care arm reported improvement 2 weeks earlier (median) than participants in the usual care arm; however, this difference was small and not statistically significant (hazard ratio 1.14, 95% confidence interval 0.89 to 1.46).
- Secondary clinical outcomes were similar across both arms of the trial. Participants in both arms improved similarly, on average, on most outcomes from baseline.
- The statistically significant result in one of the subgroup analyses should be interpreted with caution, given the small sample size.
- The primary base-case economic evaluation showed that stratified care was marginally more costly and slightly less effective (mean adjusted quality-adjusted life-year difference -0.011). In the context of the results, stratified care was unlikely to be a cost-effective option using commonly applied willingness-to-pay threshold values of £20,000-30,000 per quality-adjusted life-year gain.
- The novel aspect of the stratified care intervention, namely the fast-track to imaging and specialist opinion, was acceptable to patients and clinicians, but there was reluctance to consider invasive treatments if sciatica symptoms were of short duration.

Implications for health care

- The results of this trial do not support the use of the stratified care model tested for the management of patients consulting in primary care with sciatica symptoms.
- The trial's usual care comparison was delivered without the use of any stratification tools, and led to good clinical outcomes, on average. All usual care patients saw a physiotherapist for assessment and advice and the majority were referred for further physiotherapy treatment.
- More patients in stratified care received spinal epidural injections, but this did not lead to better outcomes than usual care.
- Fast-tracking sciatica patients to imaging and spinal specialists was viewed favourably by patients and clinicians, but clinicians, and some patients, favoured stepped care rather than stratified care when symptoms were of short duration.
- Further research should try to identify factors consistently and differentially associated with outcome or treatment effect in sciatica patients, to inform new stratified care models for sciatica.

Implications for future research

- Given that the key prognostic factors relevant in non-specific lower-back pain are not also consistent prognostic factors in sciatica, there is a need for further research to explore different stratified care models for this population.
- Other models of stratified care for sciatica could be explored, for example based on pathophysiological mechanisms, such as sensory profile differences.
- Testing ways to systematise care delivery for sciatica patients could help to reduce practice variation.

Trial registration

This trial is registered as ISRCTN75449581.

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