# The diagnostic utility and cost-effectiveness of selective nerve root blocks in patients considered for lumbar decompression surgery: a systematic review and economic model

R Beynon,[1] J Hawkins,[1] R Laing,[2] N Higgins,[2] P Whiting,[1] C Jameson,[1] JAC Sterne,[1] P Vergara[2] and W Hollingworth[1]*

[1]School of Social and Community Medicine, University of Bristol, Bristol, UK
[2]Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

*Corresponding author

## Executive summary

### Selective nerve root blocks in patients considered for lumbar decompression surgery

Health Technology Assessment 2013; Vol. 17: No. 19
DOI: 10.3310/hta17190

NIHR Journals Library

# Executive summary

## Background

During the course of a year, 36–48% of British adults recall having low back pain, with 58–62% of adults experiencing low back pain at some point in their lives. In the UK, the economic burden of back pain in terms of health-care costs and lost productivity is around £12B. In most cases, the pain will resolve after a few days or weeks, but in some patients pain may not resolve and becomes chronic. Patients with chronic pain often develop significant disability and have impaired quality of life. Patients may develop referred symptoms including pain, sensory disturbance (e.g. numbness) and weakness extending to the leg. In some patients, lower limb symptoms are caused by inflammation or compression of a spinal nerve root and this is termed lumbar radiculopathy (LR).

The exact cause of low back and leg pain may be difficult to diagnose. The distinction between radiculopathy and other types of referred lumbar spine pain is crucial for treatment planning. In carefully selected patients, decompressive lumbar surgery (e.g. discectomy) is more effective than conservative care in rapidly relieving leg pain and reducing disability. In most patients, the diagnosis of radiculopathy is made by careful correlation of clinical signs and symptoms (e.g. pain distribution, paresis, straight-leg raising test) and imaging findings (e.g. evidence of disc herniation and nerve root compression) from magnetic resonance imaging or computed tomography scans. Neither clinical findings nor anatomical imaging have perfect diagnostic accuracy and, not infrequently, the clinical and imaging findings are discordant. In patients with suspected LR in whom the clinical and imaging findings are equivocal or discordant, diagnostic uncertainty remains. Before embarking on invasive therapy (e.g. surgery) to decompress the lumbar nerve root, additional diagnostic tests such as selective nerve root blocks (SNRBs) are used to help clinicians decide between surgical and conservative care.

## Objectives

This project aimed to:

1. Conduct a systematic review (SR) to determine the diagnostic performance of SNRB in patients with probable radicular pain that is not fully concordant with the imaging findings prior to lumbar decompression surgery.
2. Evaluate whether or not the diagnostic accuracy of SNRB varies by patient subgroup (e.g. patients with suspected radiculopathy at more than one level of the lumbar spine).
3. Conduct a SR to summarise the evidence on the incidence of procedure-related complications of diagnostic SNRB.
4. Conduct a SR of previous economic studies of the use of SNRB in patients with suspected LR and develop a cost-effectiveness model to evaluate the cost-effectiveness of using SNRB in patients with discordant clinical and imaging findings, including value of information analysis.

## Methods

We developed and followed a protocol for all stages of the review. Studies were identified through searches of electronic databases, internet searches and scanning reference lists of included papers. Published and unpublished studies in any language were eligible for inclusion. Two reviewers screened titles and abstracts for relevance. Full papers of potentially relevant studies were obtained and assessed for inclusion by one reviewer and checked by a second. To be eligible for the diagnostic accuracy review,

studies had to report on patients with low back pain and symptoms in a lower limb, and the diagnostic accuracy of SNRB administered under radiological guidance had to be assessed against a reference standard for the diagnosis of LR: studies had to report sufficient data to allow extraction of a $2 \times 2$ table of test performance. To be eligible for the review of adverse events, studies had to report the administration of a diagnostic SNRB in patients with LR. Data extraction was performed by one reviewer and checked by a second. Four reviewers independently assessed the quality of diagnostic accuracy studies using the quality assessment of diagnostic accuracy studies (QUADAS)-2 checklist and discrepancies were resolved through discussion. The methodological quality of studies reporting on adverse events was not formally assessed. Data were extracted to populate $2 \times 2$ tables of test performance and were used to calculate sensitivity, specificity and 95% confidence intervals (CIs). Study estimates of sensitivity and specificity were plotted in summary receiver operating characteristic space. Random-effects meta-analysis was used to calculate summary sensitivity and specificity separately for diagnostic cohort studies that used intraoperative findings and those that used post-surgical follow-up as a reference standard. Owing to the substantial differences between the control injections used in the within-patient case–control studies, we did not pool data from these studies. Data from studies on adverse events were combined in a narrative summary.

Based on data on diagnostic accuracy from the SR, we developed a decision tree and Markov model to estimate the incremental costs and effects of adding SNRB to the diagnostic work-up of suspected LR. The effectiveness and post-treatment costs of surgery and conservative care were taken from randomised controlled trial (RCT) evidence. Evidence about additional parameters of the model was identified from the medical literature and routine data sources. We developed two models to estimate the incremental cost per quality-adjusted life-year (QALY) in patients with suspected single- and two-level nerve root compression.

## Results of the diagnostic accuracy systematic review

The searches identified 11,211 titles and abstracts; of these, 138 were considered potentially relevant, retrieved and screened as full papers. Five studies ($n = 241$ patients; range 15–83 per study) were included in the review: two within-patient case–control studies, one prospective diagnostic cohort study and two retrospective diagnostic cohort studies. In all patients in the case–control studies, the source of the radiculopathy was confirmed by concordant clinical and radiological or surgical findings prior to the use of SNRB. These concordant findings formed the reference standard against which the results of injections at the symptomatic nerve root and adjacent asymptomatic sites were compared. The diagnostic cohort studies recruited patients with suspected LR but equivocal or discordant clinical and radiological findings. These studies used intraoperative findings and/or outcome following surgery as the reference standard.

There was substantial variation in the results of the studies: sensitivity ranged from 57% to 100% and specificity from 10% to 86%. All studies were judged to be at a high risk of bias. Both within-patient case–control studies selected patients with concordant clinical and imaging findings and, therefore, their findings were judged to have poor applicability to patients with discordant clinical and imaging findings. All three cohort studies were judged to be at a high risk of bias, as the decision to perform surgery (the reference standard) was not independent of the SNRB result. The reference standard was judged to be at a high risk of bias in all five studies, as there was no gold standard for the diagnosis of radiculopathy.

Based on the two cohort studies that used an intraoperative reference standard the sensitivity was 93.5% (95% CI 84.0% to 97.6%) and specificity was 50.0% (95% CI 16.8% to 83.2%). Summary sensitivity was similar in the two studies that used post surgery as the reference standard at 93.3% (95% CI 85.8% to 97.0%), but specificity was lower at 25.6% (95% CI 5.4% to 67.5%). Owing to the differences in patient selection, type of control injection and reference standards between within-patient case–control studies and the diagnostic cohort studies we decided that it would be inappropriate to statistically combine the results of these studies.

## Results of the selective nerve root block-related adverse events systematic review

Seven studies reported on SNRB-related adverse events. Only one study reported on the complications of SNRBs as the primary outcome of interest. This study found that minor and transient complications were encountered in 98 of the 1777 total patient visits (during which 2217 injections were delivered to 1203 patients), giving an overall per-patient visit complication rate of 5.5%. One other study reported that complications were encountered in four patients (3.8%) who experienced aggravated pain for 1–2 days following SNRB. The remaining five studies (range $n = 15$–117) reported that there were no complications. None of the studies reported major or permanent complications resulting from SNRB.

## Results of the economic evaluation

Our economic model estimated that, for patients with suspected single-level nerve root compression, the addition of SNRB to the diagnostic work-up was not cost-effective, with an incremental cost per QALY gained of £1,576,000, which is greater than conventional thresholds for acceptable cost-effectiveness. SNRB was not cost-effective even when the societal savings of earlier return to work were included. The use of SNRB for suspected multilevel nerve root compression was less cost-effective. A range of probabilistic and deterministic sensitivity analyses confirmed that SNRB was unlikely to be a cost-effective method for diagnosis and planning surgical therapy. However, our conclusions were sensitive to assumptions about the continuing clinical effectiveness and cost savings of surgery beyond 1 year. Under the optimistic assumption that the economic benefits of surgery reported by RCTs at 1 year continue undiminished in subsequent years, then SNRB became cost-effective from the perspective of society, despite relatively poor diagnostic accuracy.

## Discussion

There were few studies that estimated the diagnostic accuracy of SNRB in patients with low back pain and radiculopathy who have discordant or equivocal clinical and imaging findings. Research on this topic is hampered by the lack of a diagnostic gold standard against which to compare tests such as SNRB. We identified five diagnostic accuracy studies, all at high risk of bias. Of particular concern was the fact that many studies were at risk of verification bias as patients with a positive SNRB were more likely to undergo surgery (the reference standard) than those testing negative. There was substantial variation in estimates of sensitivity and specificity across studies; sensitivity ranged from 57% to 100% and specificity from 10% to 86%. Based on the two cohort studies that used post-surgery outcomes as the reference standard, the summary sensitivity was 93.3% (95% CI 85.8% to 97.0%) and summary specificity was 25.6% (95% CI 5.4% to 67.5%). However, conclusions based on these data should be tempered because of the large CIs around specificity and the high risk of bias which affects these studies.

Two previous SRs on the topic have been supportive of the diagnostic use of SNRB. The more recent review concluded that there was ‘moderate evidence for SNRBs in the preoperative evaluation of patients with negative or inconclusive imaging studies, but with clinical findings of nerve root irritation’. Based on our review of the evidence, we believe that these conclusions are too strong. The differences in interpretation between our review and those conducted previously may be partly owing to our use of more rigorous eligibility criteria, restricting analysis to studies that provided sufficient data to construct estimates of sensitivity and specificity.

Despite case reports of serious adverse events associated with SNRB, our SR confirmed that these were very rare events. Of the seven studies identified that reported on complications and adverse events of SNRB ($n > 1500$ patients), no serious adverse events were reported. The largest case series reported minor and transient complications in 5.5% of patient visits, but no major or permanent complications.

Our economic model indicated that, in patients with suspected single-level nerve root compression, SNRB does increase the proportion of patients with an accurate diagnosis of the presence or absence of nerve root compression (59.5% vs 50%) and the proportion of patients with nerve root compression who undergo surgery (20.1% vs 18%). However, these benefits do not appear to be justified by the additional costs of testing. The incremental cost per additional case accurately diagnosed was £2674 and the incremental cost per QALY gained was £1,576,007. In comparison with other health interventions, reviewed by the National Institute for Health and Care Excellence on behalf of the NHS, this does not represent good value for money. This conclusion was the same for patients with suspected two-level nerve root compromise and was not altered in sensitivity analyses varying several key assumptions of the model, including prevalence, the diagnostic accuracy of SNRB and the impact of the SNRB result on the probability of performing surgery. The model was sensitive to assumptions about the long-term costs and benefits of surgery. If the residual improvement in quality of life (utility) scores and the savings in costs observed in the surgical arm of trials at 12 months post randomisation continues, rather than diminishes over time, then SNRB has the potential to be cost-effective, despite low specificity. However, we conclude that it is unlikely based on the current evidence that SNRB is a cost-effective method for informing the decision to operate in patients with low back and leg pain where there is doubt about the localisation of the lesion.

## Conclusions

There were few studies that estimated the diagnostic accuracy of SNRB in patients with radiculopathy and discordant or equivocal imaging findings. All studies were limited by the difficulty of making a reference standard diagnosis in all patients who were tested. The evidence that is available suggests that the specificity of SNRB is relatively low. Therefore, based on current weak evidence, it is unlikely that SNRB is a cost-effective method for determining which patients will benefit from lumbar surgery.

## Implications for service provision

Our review highlights the uncertain value of SNRBs when used for diagnostic purposes to establish whether or not clinical symptoms result from a particular nerve root. However, the distinction between diagnostic and therapeutic SNRBs is often not straightforward. Many centres combine local anaesthetic and periradicular steroid injections in order to gain both diagnostic information and, potentially, longer-term pain relief for the patient. Evidence collated in SRs confirms that transforaminal epidural steroid injections can be an effective and cost-effective part of a treatment strategy for patients with radicular pain.

Better evidence is needed to inform practice in centres that currently rely on SNRB for diagnostic information to help decide whether, or at which level, to perform lumbar decompressive surgery. These centres could perform SNRB procedures as part of research projects to improve the evidence base.

## Suggested research priorities

Our recommendations for future research are:

1. A large rigorous diagnostic cohort study to determine the diagnostic accuracy of SNRB in predicting the short-term outcome of lumbar surgery in patients with suspected radiculopathy but equivocal or discordant clinical and radiological findings.
2. Separate or nested diagnostic cohort studies to identify the optimal SNRB technique (e.g. optimal anaesthetic dose, the value of needle provocation and control injections at adjacent sites).

3. A RCT to measure the impact of diagnostic SNRB on treatment decisions and the costs and outcomes of care for (subgroups of) patients with discordant or equivocal clinical and imaging findings of nerve root compression.

## Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

## Publication

Beynon R, Hawkins J, Laing R, Higgins N, Whiting P, Jameson C, *et al*. The diagnostic utility and cost-effectiveness of selective nerve root blocks in patients considered for lumbar decompression surgery: a systematic review and economic model. *Health Technol Assess* 2013;**17**(19).

# Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Five-year impact factor: 5.596

*Health Technology Assessment* is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.hta.ac.uk/project/htapubs.asp. Print copies can be purchased from the individual report pages.

### Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

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.

### HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

### This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/111/01. The contractual start date was in August 2010. The draft report began editorial review in February 2012 and was accepted for publication in October 2012. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.



Published by the NIHR Journals Library, produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

© Queen's Printer and Controller of HMSO 2013. This work was produced by Beynon *et al*. under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.