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ORIGINAL ARTICLE

Epidural Steroids for Lumbosacral Radicular Syndrome Compared to Usual Care: Quality of Life and Cost Utility in General Practice

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Abstract

Objective: To investigate the effect of adding segmental epidural steroid injections (SESIs) to usual care compared with usual care alone on quality of life and cost utility in lumbosacral radicular syndrome (LRS) in general practice.

Design: A pragmatic randomized controlled trial. Results were analyzed using mixed models.

Setting: Primary care.

Participants: Patients (N = 50) in the acute phase of LRS.

Interventions: One epidural injection containing 80mg of triamcinolone in normal saline.

Main Outcome Measure: Back pain at 4 weeks after the start of the treatment.

Results: Both groups experienced a significant increase in quality of life in (especially) the physical domains of the Medical Outcomes Study 36-Item Short-Form Health Survey. The intervention group scored significantly better than the control group at certain time points in the physical domain. The differences were small. The cost-utility analysis showed that with a negligible loss of utility (3d in perfect health), societal costs (193,354 euros per quality-adjusted life year lost) would be saved because of more productivity in the intervention group.

Conclusions: Although the beneficial effects of SESIs are small and the natural course of LRS is predominantly favorable, we think decision makers can consider implementing SESIs in daily practice with the purpose of saving resources. Caution must be taken, and further research should be directed at identifying patient subgroups who might benefit from SESIs, with additional focus on (costs of) complications and adverse effects.

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Lumbosacral radicular syndrome (LRS) is characterized by pain that radiates from the back to below the knee in 1 leg (sciatica), with the presence of Lasègue's sign, neurologic symptoms originating from 1 nerve root, or both.[1] It is most commonly caused by lumbar disk herniation, resulting in an inflammatory response around the nerve root that causes radicular pain. The pain of sciatica is of a burning or shooting nature and significantly affects patients' general well-being because of its intensity.[2] Segmental epidural steroid injections (SESIs), which may inhibit the inflammatory response around the nerve root, are a controversial treatment in LRS.[3,4] They are effective in treating pain in the short-term, in the acute phase of a well-defined radicular syndrome with sciatica, causing few adverse effects.[5-15] SESIs are used to treat LRS in the Netherlands, but they are not recommended in the Dutch College of General Practitioners' Guideline on Lumbosacral Radicular Syndrome as a routine treatment.[1] The treatment of low back pain and sciatica is expensive as well in terms of health care costs, with 337.3 million euros (€) spent in the Netherlands in 2000.[16]

In a pragmatic randomized controlled trial, we compared the effectiveness of adding an SESI to the usual care of LRS, with usual care alone. We found a small, significant difference in favor of the intervention for back pain, impairment, disability, and patient satisfaction with treatment. A cost-effectiveness analysis showed that adding the intervention to usual care was considerably cheaper than usual care alone, mainly because of a greater loss of productivity in the control group.

Lower costs are an important economic argument for implementing an intervention that has shown clinical superiority or equivalence, but the effect on the patients' quality of life also has

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to be considered. In addition, decision makers need to be able to compare different interventions to weigh their costs and benefits. The aim of cost-utility analyses is to estimate the ratio between the cost (or savings) of an intervention and the benefit it produces in terms of years lived in full health (quality-adjusted life years [QALYs]). Cost-utility analyses therefore allow comparisons across different health programs and policies by using a common unit of measure (money/QALYs), which is why cost-utility analyses are used to guide procurement decisions. Although SESIs are a widely used additional pain treatment in LRS, little is known about their effects on patients' quality of life and their cost-effectiveness in terms of utility, and nothing is known when studied from a societal perspective or compared with other interventions in sciatica.

We therefore compared health-related quality of life in patients with acute LRS who received either usual care or usual care with an additional SESI. We also carried out a cost-utility analysis assessing the balance between QALYs gained and observed societal costs after 1 year.

Methods

Overall, 63 patients aged 18 to 65 years, in the acute phase of LRS, participated in a pragmatic randomized controlled trial comparing usual care to usual care with an additional SESI. Inclusion took place in 2005 to 2007. Patients were followed up for 1 year. Exclusion criteria were a history of spinal surgery or trauma, maintenance therapy with corticosteroids or anticoagulants, a bleeding disorder, cauda equina syndrome, a body mass index >35 kg/m^2, a mental disability, an inadequate mastery of the Dutch language, an allergy to corticosteroids, pregnancy or an active wish to conceive, and breastfeeding. The study was reviewed and approved by the institutional medical-ethical board of the University Medical Centre Groningen.

Patients who contacted their general practitioner (GP) for LRS were given written information on the study, a baseline questionnaire, and an informed consent form. The forms were completed and sent to the research center. On receiving the baseline questionnaire and the informed consent, the primary researcher contacted the subjects to check inclusion and exclusion criteria. Randomization was performed by a GP who was not otherwise involved in the study, using pre-prepared, sequentially numbered, opaque, sealed envelopes containing stickers with either "SESI" or "CAU" (care as usual), balanced after 40 assignments. On randomization, the envelope that was next in line was opened, and the sticker with the allocated treatment was fixed on the completed inclusion form. Inclusion forms were coded and kept separately from coded follow-up questionnaires. Researchers were blinded until after the final analysis of the results.

As demanded by the pragmatic study design, usual daily practice circumstances were closely followed up. All patients received care as usual according to the Dutch College of General Practitioners' Guideline on Lumbosacral Radicular Syndrome (analgesics, maintaining normal daily activities as much as possible, referral if necessary) from their GPs. Patients in the intervention group received an SESI in addition to usual care. SESIs consisted of 80mg of triamcinolone in normal saline and were administered at the department of anesthesiology pain management center of the University Medical Hospital Groningen. Both groups were followed up with questionnaires regarding pain, disability, health-related quality of life, and costs. Measuring instruments used were numeric rating scales for pain, the Roland-Morris Disability Questionnaire for disability, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) questionnaire for quality of life, and specifically developed cost questionnaires for costs. The numeric rating scale score for back pain at 4 weeks after the start of the treatment was used as the primary outcome measure for calculating sample size. We needed to include 33 subjects in each group to detect a difference of 1.2 and a common within-group SD of 1.7, as is reported in the literature as the minimal clinically important difference in back pain ($\beta = .80$, $\alpha = .05$ 2-tailed).[17,18]

List of abbreviations:

CI	**confidence interval**
EQ-5D	**EuroQol–5 Dimensions**
GP	**general practitioner**
LRS	**lumbosacral radicular syndrome**
QALY	**quality-adjusted life year**
SESI	**segmental epidural steroid injection**
SF-36	**Medical Outcomes Study 36-Item Short-Form Health Survey**
SF-6D	**Short-Form–6 Dimensions**

Quality of life

Quality of life was measured using the SF-36 health-related quality-of-life questionnaire at baseline and at 4, 13, 26, and 52 weeks after the start of the treatment.[19] Physical and mental component scores were calculated using an uncorrelated (orthogonal) factor solution.[20] Analysis was carried out on an intention-to-treat basis using mixed models. In this type of regression analysis, the mean outcomes in our study population (which provide an approximation of the mean values in the general population), were used to estimate the means in the general population. Therefore, estimated means rather than measured values are presented. Patients were a random factor in the model, with variance components as a covariance structure and treatment a fixed factor. Time of measurement was entered in the model as a categorical variable. This means time was not represented as a continuous process but as 6 seperate time points. For every outcome variable, treatment and time of measurement as independent variables were tested with sex, age, and baseline values as covariates to account for nonbalance in the randomization.

Cost utility

Our cost-utility analysis compared societal costs per QALYs at 1 year between the intervention group and the usual-care group. Since the SF-36 is not a preference-based questionnaire, the scores were transformed to utility scores using the Short-Form–6 Dimensions (SF-6D) profiling as described by Brazier et al.[21] The SF-6D includes the following health domains: physical functioning, role participation (combined role-physical and role-emotional), social functioning, bodily pain, mental health, and vitality. Areas under the curves were calculated for each patient using the standard trapezoidal method.

The economic evaluation was performed with a time horizon of 1 year from a societal perspective, which means that all direct medical, and all direct and indirect nonmedical costs including loss of productivity, were taken into account regardless of who pays for them. Unit prices were drawn from the guidelines for cost studies (methods and unit prices for economic evaluations in health care) and from online information on medication costs by the Dutch health insurance board.[22,23] The cost-utility analysis was performed, with the incremental cost-utility ratio as the main outcome.