Radiculopathy and radiating low back pain in general practice

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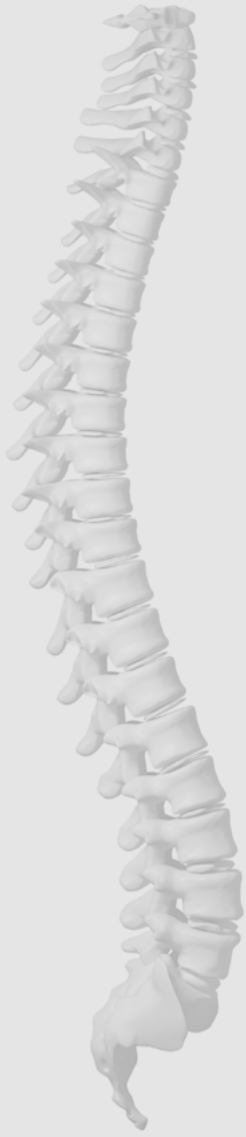
Chapter 6

Summary and General Discussion



OBJECTIVE

The main objective of this research project was to explore the current state of affairs concerning radiating low back pain and LRS in Dutch general practice, and to investigate the effectiveness, cost-effectiveness and cost-utility of adding a segmental epidural steroid injection to the analgesic treatment of LRS in the acute phase.

SUMMARY OF MAIN FINDINGS

From our cohort study, we learned that 'radiating low back pain', registered with the ICPC code L86 in Dutch general practice, signifies LRS in about 50% of cases and non-specific radiating low back pain in the other half. [chapter 2]. Since half of all the episodes of radiating low back pain consisted of only one contact between patient and GP, radiating low back pain seems to be a mostly short-term problem for which not much care is needed. Extended episodes of radiating low back pain do occur but are uncommon. These episodes appeared to be related to a medical history of non-radiating low back pain as well as to the presumed (by the GP) presence of nerve root involvement.

Segmental epidural corticosteroid injections as an additional pain treatment in general practice yielded a significant beneficial effect on back pain, disability, patients satisfaction with treatment, self-perceived impairment [chapter 3] and quality of life [chapter 5] in patients with acute LRS, as compared to usual care. The differences between groups for pain and disability were small. The differences in experienced physical and emotional role limitations as part of the health related quality of life on the other hand, were profound. Because epidural steroid injections for LRS decrease the loss of productivity [chapter 4], the intervention turned out to be cost-effective on a societal level, against a negligible loss of utility [chapter 5] and a low risk of complications and adverse effects.

STRENGTHS

To our knowledge, our study is the first pragmatic randomized trial in general practice to investigate the clinical effectiveness, cost-effectiveness and cost-utility (from a societal perspective) of epidural corticosteroid injections in the treatment

of LRS, as compared to usual care. It is also one of the very few studies that have taken place in general practice, where the majority of LRS patients are treated. Its most important contributions to the existing knowledge about this topic is that, although the impact on direct medical outcomes (pain) of this intervention is small, patients will experience a higher quality of life and more satisfaction with treatment. They will be less prone to absence due to sick leave, thereby saving societal finances. This information is important for clinicians as well as decision makers at national healthcare level.

LIMITATIONS

Despite meticulous randomization, the intervention group in our trial was in a worse initial condition than the control group [chapter 3-5]. We corrected for these differences by including baseline values as covariates in our mixed model regression analysis. However, offset differences might imply that the patients from the different study groups fall into different categories. This could be caused by a different underlying aetiology, which renders the groups incomparable, or impair the use of measuring instruments. In sciatica there is no relation between severity of symptoms and severity of disc displacement.[1] Also, minimal clinically important differences on pain scales do not vary with severity of pain, which allows their use in patient groups with different initial conditions.[2]

The measuring instruments used, numerical rating scales for pain, the Roland Morris disability score for function, the SF-36 for quality of life and the SF-6D for utility, are all recommended and well-documented in patients with LRS.[3-5] As primary outcome measure, we chose back pain, since at the time of writing our protocol, information on the MCID of low back pain patients in general practice was readily available. Leg pain, however, is a more specific measure for radiculopathy.[6, 7] Had we chosen leg pain, our conclusions would have been the same. Our study had the statistical power to detect a difference of 1.2 on a numerical rating scale with a power of 0.80 and an alpha of 0.05, and since the minimal clinically important difference for leg pain on the numerical rating scale is 1.3 to 3.5, it would have detected a relevant difference in leg pain if present.[5,21]

In pragmatic randomized controlled trials, cluster randomization is the preferred method.[8] In such randomization, physicians or practices would be assigned to the intervention group or control group, rather than the individual patients. In our study, cluster randomization was not possible because informed

consent for participating in studies that involve invasive procedures has to take place at patient level. If however, a physician has patients in both study groups, modification of his behaviour by treating patients in the intervention group may affect the care he provides to patients in the control group. In other words, our 'usual care' may have been 'better than usual'. This could have led to an underestimation of the differences between group outcomes. Additionally, since randomization took place on an individual level, patients knew to which group they had been assigned. Disappointment in the control group subjects of missing out on an extra treatment may have cause discontent with the provided usual care. This might have led to overestimation of the differences between group outcomes. We cannot tell to what extent these factors have influenced our study results.

REFLECTION AND RECOMMENDATIONS

Current reports in general practice make use of the L86 registry code to draw conclusions on the prevalence and incidence rates of, and treatment strategies for, LRS.[9-12] In fact, the populations that were studied probably include about as many cases of non-radicular radiating low back pain, as cases of LRS. Epidemiological information on LRS needs to be re-evaluated since the current incidence and prevalence rates are unreliable.

As elaborated on in the General Introduction, epidural corticosteroid injections in LRS are an efficacious and safe short-term treatment option in patients with acute and well-defined radiculopathy ('sciatica'). The effects are small, and opinions differ on whether the intervention should be implemented in practice. From our study we learned that adding epidural corticosteroid injections to the usual care in the acute phase of LRS in general practice improved patients' health-related quality of life, increased their satisfaction with the treatment given and enabled them to return to work sooner, thereby saving societal health care resources, compared to usual care alone. The beneficial effects on direct medical patient outcomes (pain and disability) on the other hand, were too small to be relevant according to our pre-set threshold.

Several factors might have contributed to these results. Firstly, as explained in the general introduction and the various method sections, we did not optimize our study circumstances beyond normal daily practice, as is dictated by the pragmatic study design. Perhaps the participating GPs did not distinguish strictly enough between non-specific low back pain and LRS for this intervention to show an effect,

despite the instructions in the guidelines. More likely, the patient population that consulted the GPs may have differed from the -hospital- populations studied in the abovementioned randomized controlled clinical trials. Another possibility is that certain subgroups of patients within our population may have benefited less from the intervention than others, causing a levelling of the mean effect. Also, the injection administration route as applied in our hospital, the interlaminar approach, is deemed less effective than the radioscopically guided transforaminal approach, which could render the intervention less effective than expected.[13, 14]

Secondly, the methodological limitation of individual randomization, rather than cluster randomization, could have diminished the effect of the intervention (see above).

Finally, as minimal clinically important difference (MCID) for our primary outcome variable we chose 1.2 on the numerical rating scale, as is reported in literature.[15,16] MCIDs, however, vary with populations and contexts.[17] When evaluating differences between groups rather than improvement within an individual, one ideally uses a between-treatment MCID, which (to our knowledge) is not available for NRS scores in low back pain. Also, the MCID in a general practice population could be different than in a hospital setting, where most research takes place. It is therefore possible that the effect found in our study could be relevant after all, although it should be noted that our threshold was already set rather low: according to many other researchers, a 30% reduction of pain intensity (for a relative change) and a 2 – 3.5 point reduction (for a crude change) on a numerical rating scale is to be considered clinically relevant in numerical rating scales for pain.[18-26]

Despite reporting only a little less pain and less impairment, patients felt and behaved as if their symptoms of LRS had markedly improved after receiving an epidural steroid injection. Unfortunately, the placebo-controlled randomized controlled trials did not focus on indirect medical outcomes, which means we are not sure whether there is evidence for efficacy in that respect. In other words, the question remains whether these positive outcomes are actual effects, or placebo effects arising from being given an extra treatment and more attention. On the one hand, decreased rates of absence through illness, increased quality of life and being more content with one's caregivers are not negligible or unimportant effects. Neither is it irrelevant or unethical to try and save healthcare resources by adding a new treatment, provided it is of at least equal effectiveness as the usual care. On the other hand, the risk of complications and side effects is small but never

zero. Implementing an intervention solely for its placebo effect would violate the 'primum non nocere' principle and can be considered quackery.

In our opinion, it might, for the time being, be the best idea to leave the question, whether or not to apply a segmental epidural steroid injection for acute LRS, in the consulting room, to be settled by patient and physician together. When administered to the right patients, SESIs are an efficacious and safe treatment for acute LRS. The fact that this does not show convincingly in our general practice population does not mean SESIs can't be useful in individual patients. This treatment should not be regarded as a black-or-white matter. Instead, it should be considered an opportunity for shared and 'trans mural' decision making between patients, GPs and medical specialists. In the meantime, continued reimbursement of epidural corticosteroids in acute LRS could provide a cost-effective course of action for decision makers in the field.

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