

SUMMARY

Introduction

Globally low back pain (LBP) causes more disability than any other condition, and has major social and economic consequences. The costs of LBP in The Netherlands are estimated at €3.5 billion in 2007. Approximately 33% of the patients will recover in the first three months, but other patients will develop chronic (more than three months) symptoms. These patients are responsible for the majority of the costs of LBP.

Over the last decades multiple structures in the lumbar spine have been considered a source of pain in the lower back, among others pain from the facet joints, sacroiliac (SI) joints, or discs. These LBP structures can be diagnosed by patient history, physical examination, imaging techniques and/or diagnostic blocks. A diagnostic block will anaesthetise a painful facet joint or SI-joint for the duration of the anaesthetic effect. The diagnosis facet joint pain or pain from the SI-joint will be made if patients report having pain reduction of minimally 50%. Despite a solid body of evidence these diagnostic blocks are currently the best tests available to diagnose LBP originating from the facet joints and from the SI-joints, and to predict the success of radiofrequency (RF) denervation procedures.

A wide variety of treatment options is available for patients with chronic LBP (CLBP) (e.g NSAIDs, exercise therapy, multidisciplinary bio-psychosocial treatment). RF denervation is one of the treatment options (performed by pain specialists) in a multidisciplinary setting for patients with CLBP presumably from a single source: facet joint, SI-joint, disc or a combination of these (defined as mechanical LBP). However, the evidence of efficacy is limited and no high quality data are available for effectiveness and cost-effectiveness. The overall objective of this thesis is to contribute to the development of a sound evidence base on the diagnostic accuracy of patient history and physical examination for CLBP originating from the facet joints; effectiveness and cost-effectiveness of the added value of RF denervation to a standardised exercise programme for CLBP; and the generalizability of these results.

Part 1: What is known about the diagnostic accuracy of patient history and/or physical examination in diagnosing CLBP originating from the facet joints?

In *chapter 2*, the diagnostic accuracy of patient history and/or physical examination in comparison with diagnostic blocks to identify facet joint pain in patients with CLBP is

described. No firm conclusions can be drawn about the diagnostic accuracy of patient history and/or physical examination compared to a diagnostic facet joint block due to the small number of studies, wide variation in index test and reference standard combinations, clinical heterogeneity, and an overall high risk of bias.

Part 2: What is the effectiveness and cost-effectiveness of RF denervation for CLBP originating from the facet joints, SI-joints, discs or a combination of those structures?

Chapter 3 provides a state-of-the-art systematic literature review of the effectiveness of RF denervation for the treatment of patients with CLBP. Low to moderate quality evidence shows small effects for facet joint RF denervation for pain reduction and improvement in functional status compared to placebo. RF denervation for the treatment of the SI-joints or discs show conflicting results. Overall, we found no high-quality evidence suggesting that RF denervation provides pain relief or improves functional status for patients with CLBP.

Chapter 4 presents the design of four randomised controlled trials (RCTs) and an observational study. *Chapter 5 through 7* describes the results of three RCTs on the effectiveness and cost-effectiveness of RF denervation added to a standardised exercise programme compared to a standardised exercise programme alone for patients with CLBP who are referred to a pain clinic.

Chapter 5 suggests that facet joint RF denervation is not effective when added to a standardised exercise programme. *Chapter 6* shows statistically significant effects in pain reduction, improvement in functional status and global perceived effect in the short term for patients with chronic SI-joint pain. No long-term differences in effects were found. *Chapter 7* shows statistically significant results for RF denervation three months after the start of the intervention for pain reduction when used for patients with CLBP originating from a combination of the facet joint, SI-joints and/or disc. At the 12 months follow-up assessment there was a statistically significant difference in functional status in favour of the control group.

RF denervation added to a standardised exercise programme cannot be considered cost-effective when used for patients with CLBP originating from the facet joints, SI-joints, or a combination of facet joints, SI-joints and/or discs.

Part 3: Is the course of LBP symptoms in RCTs comparable to the course of LBP symptoms in observational studies?

Chapter 8 shows no clinically relevant differences in course of LBP symptoms between randomised study groups and matched observational study groups for patients with CLBP originating from the facet joints or SI-joints who were treated with RF denervation and an exercise programme. The unmatched observational groups show somewhat worse outcomes. Overall, this chapter shows that results from a RCT are generalizable to clinical practice.

Discussion

Based on this thesis, it can be concluded that RF denervation added to a standardised exercise programme shows short-term effects for CLBP origination from SI-joints and CLBP from a combination of the facet joint, SI-joint and/or disc. RF denervation did not show additional effects in the treatment of facet joints. Neither can RF denervation for CLBP originating from the facet joints, SI-joint, or a combination of the facet joints, SI-joints and/or discs be considered cost-effective. While interpreting these results, two considerations should be taken into account: 1) the lack of a gold standard for diagnosing CLBP originating from the facet joints, SI-joints and/or discs; 2) it should be questioned if the short-term effects from our non-blinded trials are clinically relevant. Future research should focus on identifying subgroups of patients with CLBP that might benefit from RF denervation in a multidisciplinary setting and it is important to define a clear definition of clinical relevance when performing future research. The frequent and indiscriminate use of RF denervation should be reconsidered and RF denervation should be performed in a multidisciplinary setting for research purposes. Patients should be well informed about the benefits, harms, and costs of RF denervation.