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EFFICACY OF EPIDURAL STEROID INJECTIONS IN TREATMENT OF LUMBAR SPINAL STENOSIS

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ABSTRACT

Epidural steroid injections (ESI) are used as a conservative therapy for treating lumbar spinal stenosis (LSS), yet there is no concrete justification for them. Data from a randomized control trial evaluating the effectiveness of ESI in LSS patients was analyzed. Main outcomes were measured by French-translated LSS symptom severity, physical function, and satisfaction scales over 3 months. The first stage of the analyses evaluated psychometric properties of the scales and showed high internal consistency and test-retest reliability. The main analyses addressed ESI efficacy. Repeated measures analysis of variance over the first 3 months showed a marginally statistically significant improvement in symptom severity, physical function, and satisfaction in the ESI group, compared to placebo. Treatment effectiveness tended to decrease over time. Differences between groups were not significant at 6 and 12 months. All scales had a significant interaction between treatment and high blood pressure (HBP): subjects without HBP responded substantially better.

RÉSUMÉ

Les infiltrations épidurales de corticoïdes (IEC) sont utilisées pour traiter de façon conservatrice la sténose spinale (SS). Cependant, leur utilisation ne repose sur aucune base scientifique. Des données provenant d'un essai contrôlé randomisé évaluant l'efficacité des IEC chez les patients avec SS ont été analysées. La mesure d'effet principale a été évaluée par trois échelles spécifiques pour la SS, traduites en français, soit la séverité des symptômes, la capacité à la marche et la satisfaction des patients, sur une période de 3 mois. La première étape de l'analyse a consisté à évaluer les propriétés psychométriques des échelles qui ont démontré une très bonne cohésion interne et une très bonne fiabilité. Les analyses principales ont porté sur l'efficacité des IEC. Une analyse de variance des mesures répétées pour les 3 premiers mois a démontré une amélioration statistiquement significative de la sévérité des symptômes, de la capacité à la marche et de la satisfaction dans le groupe IEC, comparé au groupe placebo. L'efficacité du traitement a eu tendance à diminuer avec le temps. Les différences entre les groupes n'étaient pas signifivatives à 6 et 12 mois. Toutes les échelles ont montré une interaction significative entre le traitement et l'hypertension artérielle (HTA): les patients sans HTA ont beaucoup mieux répondu au traitement.

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STATEMENT OF ORGINALITY

The study reports on the first double blind randomized control trial of epidural steroid injections in treatment of patients exclusively with lumbar spinal stenosis (LSS). This research was supported by grant #96089 from the Arthritis Society (Canada). The idea for the study originated from the late Dr. Charles Rivest (Division of Rheumatology, Department of Medicine, Centre Hospitalier de l'Université de Montréal). The protocol submitted to the Arthritis Society (Canada) for funding was written by Dr. Charles Rivest with advice from Dr. Luc Fortin (Division of Physiatry, Department of Medicine, Centre Hospitalier de l'Université de Montréal). Both of the co-principal investigators, Dr. Charles Rivest and Dr. Luc Fortin, were responsible for recruitment and collection of data for the trial. Ms. Francine Bujold was the research assistant responsible for ensuring timely completion of questionnaires by the study subjects throughout the entire study period. Ms. Bujold was also responsible for all data entry.

The entire reliability and validity study of the French language LSS scale measures was conducted by me with supervision from Dr. Michal Abrahamowicz and Dr. Luc Fortin. This included data cleaning, statistical programming, decisions on statistical methods of the analyses, and interpretation of the results. The decisions on statistical methods used for the main analysis of the trial were also made with guidance from my research supervisors. The statistical analysis for the randomized control trial was conducted entirely by me. The original study protocol was used to aid in the writing of Section 4.1 of this thesis, which describes in detail, the original study design. All other sections of this thesis were written entirely by me.

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ABBREVIATIONS

CHUM	Centre Hospitalier de l'Université de Montréal
CI	Confidence interval
CT scan	Computed tomography scan
ELAI	Epidural local anesthetic injections
ES	Effect size
ESI	Epidural steroid injections
HBP	High blood pressure
HD	Herniated disks
HUI-III	Health Utilities Index --Mark III
ICC	Intraclass correlation coefficient
LSS	Lumbar spinal stenosis
MOS	Medical Outcomes Study
MRI	Magnetic resonance imaging
NSAIDs	Non-steroidal anti-inflammatory drugs
QBPDS	Quebec back pain disability scale
RAMQ	Régie de l'Assurance Maladie du Québec
SD	Standard deviation
SF-36	Short Form 36 item questionnaire
SF-36m	Physical Component Summary – Short Form 36 scale
SF-36p	Mental Component Summary – Short Form 36 scale
SRM	Standardized response mean
TENS	Transcutaneous electrical nerve stimulation
VAS	Visual analog scale

CHAPTER 1: INTRODUCTION

Lumbar spinal stenosis (LSS) is a common spinal disorder defined as a narrowing of the spinal canal or vertebral foramina (Arnoldi *et al.*, 1976) which may produce various degrees of pain and functional disability. The prevalence of degenerative LSS seems to peak between the sixth and seventh decades of life (Grabias, 1980; Spengler, 1987). As the current population continues to age, the number of diagnosed cases of LSS will also be on the rise. Current conservative treatment modalities include rest, analgesics, physical therapy, and epidural steroid injections (ESIs) (Simotas *et al.*, 2000). Patients with severe pain due to LSS, that is not relieved by conservative therapy, may require surgery. However, conservative management may be the only viable option for many elderly patients that display comorbid illnesses presenting high surgical risk. (Rydevik *et al.*, 1997). Although there is some evidence that many patients have responded well to conservative therapy, current literature on the efficacy of ESI in treating LSS is controversial (Rydevik *et al.*, 1997; Koes *et al.*, 1995; Schneeberger *et al.*, 1998). ESI studies restricted to LSS patients have generally reported improvement in between 48% (Hoogmartens & Morelle, 1987) and 69% (Abanco *et al.*, 1994) of treated patients, with some reporting an average beneficial effect to last 2-3 months (Radu & Menkes, 1998), and possibilities of prolonged relief lasting up to 10 (Ciocon *et al.*, 1994) or 12 months (Abanco *et al.*, 1994). Most of these studies have not been randomized or properly controlled (Ciocon *et al.*, 1994; Fukusaki *et al.*, 1998; Hoogmartens & Morelle, 1987; Radu & Menkes, 1998), and have had small sample sizes resulting in low power (Hoogmartens & Morelle, 1987; Ciocon *et al.*, 1994). Outcome measures in LSS studies have not included reliable, valid, and responsive scales that address patients' concerns related to quality of life such as symptom relief, functional improvement, and satisfaction due to their ESI treatment. In particular, no such outcome measure has a validated French version.

This thesis has two main objectives. The first objective is to use the data from a recently completed randomized controlled trial to evaluate the efficacy of ESI in LSS patients. The second objective is to evaluate the properties of French language versions

of published LSS scales measuring symptom severity, physical function, and satisfaction in LSS patients undergoing ESI treatment.

CHAPTER 2: BACKGROUND

2.1 Lumbar spinal stenosis

In 1891, Gowers (1891) first reported that a narrowing of the foramina may damage nerve roots and that radiating pain may be produced, including a descending neuritis. In 1899, Sachs and Frankel (1900) described a condition in patients with lumbar or lower-extremity pain who walked with a bent forward position and were relieved of pain with laminectomy. A few decades later, Putti (1927) described these concepts as they related to the clinical presentation, pathology and treatment of what was later defined as 'lateral degenerative stenosis' by Verbiest (1954). Lumbar spinal stenosis (LSS), as it was later defined, is a condition involving any type of narrowing of the spinal canal, nerve root canals, or intervertebral foramina caused by bone or ligament hypertrophy in local, segmental or generalized regions (Arnoldi *et al.*, 1976). LSS can be congenital or degenerative in nature, the latter being most common in the elderly with a peak prevalence between 60-70 years of age (Grabias, 1980; Spengler, 1987).

The natural evolution of LSS is characterized by a slow progression and symptoms have not been seen to deteriorate even four years after the initial diagnosis (Johnsson *et al.*, 1992). Johnsson *et al.* (1992) reported that the status of 70% of patients was unchanged while 15% were even found to improve after 49 months of observation in patients not on any therapy. He concluded that invasive therapy such as surgery should only be recommended in patients with intolerable pain or who develop neurologic symptoms (Johnsson *et al.*, 1992).

Specific symptoms of LSS vary from patient to patient, although key symptoms include: mild to severe pain in lower back or buttocks, developed from walking or other activities and worsened with exercise; radiating leg pain in one or both thighs and legs brought forth by walking as a result of neural structure impingement (neurogenic intermittent claudication) (Nowakowski *et al.*, 1996); numbness, weakness, paresthesia or a feeling of 'pins and needles' involving the lower extremities; with symptoms relieved by bending forward, sitting or lying down (spine flexion). Neurogenic intermittent claudication can be more formally defined as the onset of pain, tension, and weakness upon walking in one or both legs, which progressively increase until walking becomes impossible, but subsequently disappears after a period of rest (Verbiest, 1976).

2.2 General management of LSS

These symptoms are more likely to occur in the elderly population, therefore an increase in the prevalence of LSS will occur with an aging population. In adults older than 65 years, degenerative LSS is the most common reason for lumbar spinal surgery in the United States (Deyo *et al.*, 1992; Turner *et al.*, 1992). Although surgery is not the first treatment option for LSS, it is considered in patients with moderate to severe LSS where conventional conservative therapy has failed. Currently, the diagnosis, management and treatment of LSS remain controversial.

Conservative management of LSS has included bed rest (Fast, 1988), corsets, nonsteroidal anti-inflammatory drugs (NSAIDS) (Deyo, 1996), narcotics (Levy *et al.*, 1992), physical therapy (Nguyen, 1996), postural rehabilitation, spine manipulation (Fast, 1988), transcutaneous nerve stimulation, analgesics (Deyo, 1996), and epidural steroid injections (ESI) (Radu & Menkes, 1998). In severe LSS, where conservative therapy is shown not to be effective, surgery may be recommended depending on patient comorbidity. Herno *et al.* (1996) reported that in patients with moderate LSS, no significant difference in improvement was found between surgical and conservative management. However, patients were not randomized, resulting in the risk of confounding the treatment effect by possible difference in average symptom severity between the two groups (Herno *et al.*, 1996).

2.3 Epidural injections

2.3.1 Epidural local anesthetic injections (ELAIs)

In 1885, Corning (1885) was the first to recognize the anesthetic potential of thoracolumbar epidural injections while Sicard (1901) in 1901, was the first to use epidural injections via the sacrohiatal route in the treatment of sciatica and low back pain. The first Canadian study published in this area, conducted by Viner (1925) in 1925, found caudal extradural injections as an effective treatment for sciatica. In 1930, Evans (1930) found complete relief of sciatic symptoms in over 60% and symptom improvement in 14% of 40 patients treated with intrasacral epidural injections containing either physiologic saline or novocaine alone, or both in combination. Later studies have

found simultaneous treatment of patients with local anesthetic and steroids, to be more effective in alleviating pain than local anesthetic alone (Swerdlow & Sayle-Creer, 1970).

2.3.2 Epidural steroid injections (ESI)

In 1950's, corticosteroids were first introduced into epidural injections by Lièvre *et al.* (1957). Hydrocortisone was injected in 46 patients with sciatica. Very good or good results were seen in 50% of patients. The rationale behind the use of epidural steroids in low back pain has been one of economic and physiologic reasoning. It has been suggested that steroids work by relieving inflammation at the lumbar nerve root (Lindahl & Rexed, 1951; Barry & Kendall, 1962). Work by Lindhal and Rexed (1951) suggested that sciatic pain from mechanical pressure was further exacerbated by neural inflammatory changes due to chemical byproducts of disk degeneration. Use of epidural steroids could also prevent the unnecessary costs and invasiveness of surgery (Weber, 1983; Saal & Saal, 1989).

Over the past three decades, many randomized trials have been undertaken to assess the efficacy of epidural steroid injections in treatment for sciatica and low back pain (Carette *et al.*, 1997; Bush & Hillier, 1991; Ridley *et al.*, 1988; Mathews *et al.*, 1987; Cuckler *et al.*, 1985; Klenerman *et al.*, 1984; Yates, 1978; Breivik *et al.*, 1976; Dilke *et al.*, 1973; Beliveau, 1971; Serrao *et al.*, 1992; Rocco *et al.*, 1989; Snoek *et al.*, 1977). Five of these studies found epidural steroid injections to be an effective treatment option (Bush & Hillier, 1991; Ridley *et al.*, 1988; Yates, 1978; Breivik *et al.*, 1976; Dilke *et al.*, 1973), while eight studies found epidural steroid injections to be associated with worse outcomes or no benefit (Carette *et al.*, 1997; Mathews *et al.*, 1987; Cuckler *et al.*, 1985; Klenerman *et al.*, 1984; Beliveau, 1971; Serrao *et al.*, 1992; Rocco *et al.*, 1989; Snoek *et al.*, 1977). A critical appraisal of these 13 trials was conducted by a French Task Force of Randomized Trials, which revealed methodological weaknesses in most of these studies and reported that no conclusive evidence exists as to the efficacy of ESIs in treating low back pain and sciatica (Rozenberg *et al.*, 1999).

2.4 Use of ESI in treatment of LSS

Use of ESIs as an effective treatment option for LSS is currently controversial (Rydevik *et al.*, 1997; Koes *et al.*, 1995; Schneeberger *et al.*, 1998). In 1990, 6491

epidural steroid injections were billed to the Régie de l'Assurance Maladie du Québec (RAMQ, 1997) for the treatment of patients with painful back disorders including spinal stenosis, disk herniation, sciatica and spondylosis. It was estimated that 15% to 30% (Fortin, 1997) of these injections were performed on patients with LSS, corresponding to 970 to 1940 procedures per year. Variation in this estimate is due to the substantial differences in referral patterns of providing centers.

To date, most research has focused on the efficacy of ESI in chronic back pain populations with mixed etiology and has included few subjects with LSS (Abanco *et al.*, 1994; Cohn *et al.* 1986; Cuckler *et al.*, 1985; Fukusaki *et al.*, 1998; Jamison *et al.* 1991; Rivest *et al.* 1998; Rosen *et al.* 1988; White *et al.* 1980). Table 1-1 summarizes information on published studies to date, which have included LSS patients. Literature search with MEDLINE indicated no reports on randomized controlled trials that have been performed to assess the effectiveness of ESI specifically in LSS patients.

2.4.1 Low back pain studies on patients with mixed etiology

In 1980, White *et al.* (1980) prospectively studied 304 consecutive patients with low-back pain resulting from various causes. All patients underwent ESI therapy. Of those with LSS, 93% found the ESI to relieve pain after one day, but only 21% were still relieved of pain at two months, and 1.5% continued to be relieved at six months. The interpretation of the results of this study is limited because of the lack of control group. Moreover, although study outcomes were based on a scale designed to measure pain and functional status (White *et al.*, 1980), this scale had not been validated.

Cuckler *et al.* (1985) reported on what appears to be the only randomized placebo-controlled trial of ESI including LSS patients. Thirty-seven patients with LSS and 36 patients with acute herniated disks(HD) were randomly assigned either to epidural injections with 7 mL of methylprednisolone acetate and procaine (treatment group) or physiological saline solution and procaine (placebo). Patients were blind with respect to which trial arm they were randomized to. In both LSS and HD patients, steroid treated

TABLE 1-1: Summary of published studies of epidural steroid injections including patients with lumbar spinal stenosis

Author (year)	Patients LSS others	Mean Age (yrs)	Diagnosis (mean symptom duration)	Mean Follow-up (months)	Methods	Outcome Measures	Evaluation Timepoint(s)	Results
White *et al* (1960)	ND 304	range given (21-87)	Low back pain (ND)	24	Prospective uncontrolled	Pain Grading Scale (0 to 10 where 0=no pain, 5=pain enough to feel antisocial, 10 = most severe, enough to think about suicide)	1 day 2 weeks 1, 2, 3, 6+ months	No validated pain grading and functional rating scales, for LSS, 93% improved at 1 day, 21% at 2 mo and 1 5% at 6 mo (respectively 82%, 16%, and, 7% for non-LSS)
Cuckler *et al* (1985)	37 36	49	LSS and HD (37 ± 13 months)	13	Prospective placebo controlled randomized double blinded	Subjective improvement recorded by physicians blinded to treatment type	1 day 13-30 months (mean, 21 mo)	Success defined as >75 % of improvement, improvement in both saline and steroids groups, no superiority of steroids compared to saline
Cohn *et al* (1986)	3 17	ND	Recurrent low back pain (12 7±3 5 yrs)	24	Prospective uncontrolled (steroids+morphine)	Pain VAS	every month for 2 years	Specific results for LSS are ND, for the total group 100, 75 or 50 % of relief at 6 months in respectively 12, 5 and 3 patients
Hoogmartens and Morelle (1987)	38	63	LSS (ND)	23	Retrospective uncontrolled, 1 or multiple injections (mean # injections per patient = 5)	Patients asked to recall response as excellent, good, fair or poor (no definition provided)	NA	Excellent, good, fair, poor, seen in respectively 1(3%), 11(29%), 6(16%), 20(52%) patients, better response see with symptom duration <3yrs, avg walking distance increase from <100m to 1900m, poor result associated with motor weakness and reflex changes
Rosen *et al* (1988)	ND 40	55	LSS and HD (ND)	8	Prospective uncontrolled	Physician asked patients to rated pain from 1 to 10 (0 =no p ain and 10 = pain before injection)	immediate 3-24 months (mean, 8)	Specific results for LSS are ND, <2 months after injection, 60% with complete relief, and 40% no relief (% with partial relief is ND), >2 months after injection 25% complete, 32% some and 43% no relief, 50% non satisfied
Jamison *et al* (1991)	86 163	67	Low back pain (3 4±7 5† yrs)	0 5	Prospective uncontrolled	VAS for pain, BSI for emotional distress, comprehensive pain questionnaire	1 day 2 weeks	Specific results for LSS are ND, overall improvement in 62 6% of patients, no prognostic variable identified at 2 weeks
Ciocon *et al* (1994)	30	76	LSS (4 2 ± 1 9 months)	10	Prospective uncontrolled (all received 3 ESIs)	Roland's 5-point pain-rating scale (0=absence of pain, 5=almost unbearable pain)	2, 4, 6, 8, 10 months	Mean pain score of 3 4 ± 0 8 at baseline and 1 5 ± 0 9 at 2 months, signif improvement up to 10 months, with no need for other treatment modalities, no loss to follow-up over study,
Abanco *et al* (1994)	76 124	50*	LSS and HD	12	Prospective uncontrolled (treatment for radicular compression)	unvalidated LaSalle scale	immediate 1 month 3 months 6 months	Favourable response to ESI seen in 69% of patients with central LSS (n=32) and in 91% of patients with segmental LSS (n=44)
Fukusaki *et al* (1998)	53	70	LSS (2 6 ± 2 0 months)	3	Prospective uncontrolled, (all with pseudoclaudication) (all received 2 ESIs in first week)	Patient walking distance, excellent, good, and poor effect defined respectively as ability to walk >100m, 20-100m, < 20m	1 week 1 month 3 months	All patients had poor walking distance at baseline(< 20m), significant improvement in walking distance between saline and either ELAI or ESI+ELAI group after one week No difference after 1 or 3 months No effect of ESI on pseudoclaudication
Radu *et al* (1998)	62	72	LSS (1-2 yrs)	ND	Retrospective uncontrolled	Assessed benefit only on clinical grounds (no explanation)	NA	Duration of beneficial effect of ESI found to be 2-3 months (range 2 weeks to one year), at time of study only 26 patients had been given ESI
Rivest *et al* (1998)	42 36	67	LSS and HD (3 4 yrs)	0 5	Prospective uncontrolled	Difference in VAS pain score (pre-ESI vs 2 weeks post-ESI), BSI for emotional distress, comprehensive pain questionnaire	2 weeks	16 (38%) LSS patients found some degree of pain relief after 2 weeks, LSS patients improved less after 2 weeks than HD patients, predictors of poor outcome (VAS dif) in HD+LSS patients included diagnosis of LSS & report of health problems

ND = no data or not determined, NA = not applicable, ESI = epidural steroid injection, ELAI = epidural local anesthetic injections, LSS = lumbar spinal stenosis, HD = herniated disks, VAS = visual analog scale, BSI = Brief Symptom Inventory
† data provided by the authors, * approximate age of combined LSS-HD study samples

groups reported greater improvement than placebo, but the differences were not statistically significant. A drawback to this study is that primary outcome was subjectively measured at 24 hours post-injection, with failures defined as those with less than 75% improvement or requiring a second injection. This stringent response criterion was most probably too restrictive in such a small sample (n=37), which might have produced insufficient statistical power to detect significant differences between groups. Moreover, the results from another study suggest that display of improvement can take upwards of three weeks to be recognized in a significant portion of LSS patients receiving ESIs (18-25%) (Rosen *et al.*, 1988), which may explain the lack of response at 24 hours in Cuckler's study.

Abanco *et al.* (1994) studied the effect of ESI on radicular compression in a case-series of 124 HD patients and 76 LSS patients. The main outcome of the study was an unproven measure called the LaSalle scale. There is no information on the psychometric properties of this scale. Although this is not a valid or reliable measure, a so called 'positive therapeutic response' was seen in 65% of HD patients, 69% of central LSS patients, and in 91% of segmental canal stenosis patients. Improvements from ESI were sustained in some patients for as long as one year (Abanco *et al.*, 1994). In addition to being uncontrolled and nonrandomized, the study was also limited because there was no adjustment for potential covariates nor an indication of potential inclusion or exclusion criteria.

Recently, Rivest *et al.* (1998) conducted an observational prospective study on the effectiveness of ESI at 2 weeks in 42 patients with LSS and 36 patients with herniated disk (HD). At 2 weeks, 38% of LSS patients experienced improvement in Visual Analog Scale (VAS) pain scores (change in pain score between pre-injection and 2 weeks >0). However, there were limitations to this study. First, although this study is more clinically relevant than the study by Cuckler *et al.* (1985) because outcome was measured at 2 weeks instead of 24 hours, it is limited because improvement could take longer than three weeks to manifest in up to 25% of patients (Rosen *et al.*, 1988). The study is also limited because pain improvement was not evaluated after a second or third injection.

2.4.2 Studies focusing exclusively on LSS patients

Four uncontrolled studies have exclusively reported the use of ESIs in treatment of LSS (Ciocon *et al.*, 1994; Fukusaki *et al.*, 1998; Hoogmartens & Morelle, 1987; Radu & Menkes, 1998). Most of these studies have suggested some beneficial short-term effect of ESI in LSS, but lack of randomization or true controls, small sample size, variability in time of outcome measures, of steroid doses, and of route of administration, have limited the interpretation, comparability and generalization of the results. In 1987, Hoogmartens and Morelle (1987) performed a long term retrospective study (mean follow-up of 23 months) on 38 patients who underwent ESI treatment for LSS. A major drawback to this study was that the operational definition of the outcome of improvement was not explained in the paper. Improvement, it seemed, was arbitrarily assigned as excellent, good, fair or poor. With this in mind, the authors found excellent to good response in 32% of patients, fair response in 16% and poor response in 52%. Of those who reported fair to excellent response, walking distance increased on average from less than 100 m to over 1,900 m (range 200-5,000 m). Patients received a mean of 5 injections (range 1 to 26). Good or excellent outcome was correlated with short duration of previous symptoms (<3 years), but was not correlated with age, number of injections nor increased follow-up. Poor outcomes were associated with abnormal CT scans and/or myelograms, motor weakness and reflex changes (Hoogmartens & Morelle, 1987).

Ciocon *et al.* (1994) conducted a prospective study of 30 LSS patients receiving one ESI every week, for three weeks. According to MRI results, 90% of patients presented with mild to moderate LSS. The Roland 5-point back pain rating scale (0 = no pain to 5 = almost unbearable pain) was administered to measure pain levels every two months for up to ten months (Roland & Morris, 1983). Significant improvement in pain compared to baseline (pre-injection) was seen throughout the ten month follow-up, with the greatest improvement occurring between two and six months. In the only three patients with severe LSS (level 5), ESI treatment decreased pain to moderate levels after 2 months (level 2) in two patients and down to level 3 (experiencing quite bad pain) in the remaining patient. Towards the end of the study, these three cases returned to level 4 (experiencing very bad pain). Due to the lack of controls the results of this study can only be generalized with reservation to those with mild to moderate LSS.

In 1998, Fukusaki *et al.* (1998) reported the effectiveness of epidural local anesthetic injections (ELAI) alone versus ESI combined with ELAI in LSS patients with neurogenic claudication. Outcome was measured by walking distance. Inclusion in the study was limited to patients with neurogenic claudication and ability to walk less than 20 meters (mean, 10 $\pm$ 8 meters). No beneficial effect of ESI was found in treating neurogenic claudication as compared with treatment of ELAI alone. Neurogenic claudication is a good diagnostic indicator of LSS, but not all LSS patients may present this symptom (Katz *et al.*, 1994), thus results from this study may not be applicable to the entire LSS population. The authors' decision to include only those patients with ability to walk < 20 meters further limits applicability of the study to patients with exceptionally severe neurogenic claudication. A study by Radu & Menkes (1998) reported over 65% (30 of 46 patients) of patients with neurogenic claudication able to walk more than 100 meters. Most studies have used ability to walk < 100 m as their first category indicative of severe claudication (Abanco *et al.*, 1994; Radu & Menkes, 1998; Hoogmartens & Morelle, 1987). Moreover, the use of walking distance as the only outcome measure limits applicability and comparisons with most other LSS studies, which report pain improvement as the primary outcome (Ciocon *et al.*, 1994; Cohn *et al.*, 1986; Jamison *et al.*, 1991; Rivest *et al.*, 1998; Rosen *et al.*, 1988; White *et al.*, 1980). Thus, inclusion of a LSS sub-population with severe neurogenic claudication and a restricted definition of the outcome limit the applicability of these results to the general LSS population.

The above review of literature shows that most studies attempting to evaluate the effectiveness of ESI suffered from important methodological limitations. Median sample sizes of LSS patients in these studies ranged from 3 to 86, with all but one study being uncontrolled and only 4 of 11 studies exclusively studying LSS patients (Ciocon *et al.*, 1994; Fukusaki *et al.*, 1998; Hoogmartens & Morelle, 1987; Radu & Menkes, 1998) (See Table 1-1). Of these latter four studies, three did not use a validated outcome measure to assess improvement (Fukusaki *et al.*, 1998; Hoogmartens & Morelle, 1987; Radu & Menkes, 1998). Fukusaki *et al.* (1998) used walking capacity as outcome, but the sample was limited to patients with severe LSS. The one study that was a prospective randomized controlled study assessed both HD and LSS patients together and also failed to assess improvement with a valid or reliable measure (Cuckler *et al.*, 1985). Instead this

study used subjective improvement by the blinded physician as outcome (Cuckler *et al.*,1985). Moreover, in this study assessment of improvement may have been done too early to detect a significant treatment effect (Cuckler *et al.*,1985). Thus, it is clear that further randomized controlled trials must be conducted to assess the effectiveness of ESI treatment in an exclusive population of LSS patients using validated and reliable outcome measures.

2.5 Outcome assessment in LSS

Some variability in the published findings regarding improvement amongst LSS patients undergoing ESI treatment maybe due to the differences in outcome measures, lack of standardized outcome measures, variable follow-up period, and disparity in the doses and route of injection administration. Although there have been developments of standardized outcome measures for low-back pain (Kopec *et al.*, 1995; Roland & Morris, 1983; Fairbank *et al.*, 1980), with one also having been validated in the French language (Kopec *et al.*, 1995), there are few that comprehensively address the neuroischemic qualities specific to LSS. In order to complement these scales, reliable and valid measures need to be developed and implemented which also address specific concerns of LSS patients such as symptom and functional improvement.

An important measure to clinicians is patient satisfaction from a specific treatment. To date, only one standardized measure has been developed to gauge satisfaction in LSS patients, and in particular satisfaction from surgery (Stucki *et al.*, 1996). There are no standard patient-derived measures of satisfaction from ESI treatment in LSS patients, although Stucki and colleagues (1996) have developed and tested English language symptom severity, physical function, and satisfaction scales on LSS patients undergoing decompressive surgery. Assessment of the psychological testing (i.e. psychometric properties) of these scales showed that they are valid, reliable and responsive to change (Stucki *et al.*, 1996). Test-retest reliability was found to range from 0.82 to 0.96, internal consistency as measured by Cronbach alpha (Cronbach, 1951) to be from 0.64 to 0.92, and responsiveness from 0.96 to 1.07 using the standardized response mean (SRM) which indicates very good responsiveness, according to Liang *et al.* (1990). Responsiveness in a study of LSS surgical outcomes (Stucki *et al.*, 1995) using the

specific LSS scales was compared with extensively validated instruments in back pain research such as the Roland (Roland & Morris, 1983) and Sickness Impact Profile (SIP) scales (Bergner *et al.*, 1981). Both scales were found to be less responsive than the LSS specific scales, with a SRM of 0.77 and 0.69 respectively. Moreover, the LSS scales were found to be much simpler and shorter to administer than the SIP. Clarity and shortness of questionnaires such as the LSS scales, which take less than 5 minutes to complete, are important considerations when working with an elderly LSS population.

Excellent psychometric characteristics of the LSS symptom severity, physical function and satisfaction scales developed by Stucki *et al.* (1996) make them desirable outcome measures for assessing effectiveness of ESI in LSS patients. However, in order to be applicable to a LSS study of ESI efficacy in a French-Canadian population, LSS specific scales such as those proposed by Stucki *et al.* (1996) have to be adapted using cross-cultural validation standards (Bullinger *et al.*, 1993; Guillemin *et al.*, 1993; Guyatt, 1993). Recently the French-language versions of the scales have been developed by Dr. Charles Rivest (Notre-Dame Hospital, Montreal, Quebec) and Dr. Luc Fortin (Quebec Institute of Research in Physiatry, Montreal, Quebec). Yet, the psychometric properties of the French-translated scales remain to be evaluated.

2.6 Conclusion

Research in the area of epidural steroid injection therapy for lumbar spinal stenosis patients is insufficient and requires further study. Studies to date have been uncontrolled, too restrictive and most involved insufficient sample sizes. There have been no randomized control studies that have investigated the effects of ESI in LSS patients exclusively.

Moreover, assessment of treatment improvement has not been possible until the recent development of an English language LSS-specific measure that has been shown to be reliable, valid, and responsive to change (Stucki *et al.*, 1996). The LSS measurement scale was used to assess patient improvement in symptom severity, physical function and satisfaction from decompressive surgery. Although the scale enables clinicians to observe patient relevant improvements in measures such as pain, symptom severity and

physical function, a French language version of the scale has not been developed or validated.

CHAPTER 3: OBJECTIVES

This thesis has two interrelated objectives. The main goal of the study is to assess the effectiveness of ESI in improving outcomes in LSS patients. This is based on the results of a recently completed placebo-controlled randomized clinical trial in which outcomes are assessed using questionnaires developed by Stucki *et al.* (1996) for measuring symptom severity, physical function, and satisfaction in LSS patients. In order to assess the effectiveness of ESI in patients with LSS in this study, the questionnaires were translated into French and certain modifications were made to the scales. Thus, the second objective is to evaluate the psychometric properties of the French-translated versions of the LSS-specific scales developed by Stucki *et al.* (1996). Thus, the two objectives of the thesis are:

1. To evaluate the reliability, validity, and responsiveness to change of LSS-specific French language instruments measuring symptom severity, physical function and satisfaction.

2. To evaluate effectiveness of epidural steroid injections in treating lumbar spinal stenosis patients in a recent completed randomized controlled trial by assessing improvement in the above LSS scale measures in the first three months of the treatment, and to verify whether the expected effects last at 6 and 12 months.

CHAPTER 4: METHODS

4.1 Design of the original study

This thesis relies on the data collected within a double-blind randomized controlled trial, conducted by the co-principal investigators Dr. Charles Rivest (Notre-Dame Hospital, Montreal, Quebec) and Dr. Luc Fortin (Quebec Institute of Research in Physiatry, Montreal, Quebec), to study the effectiveness of administering caudal epidural steroid injections in LSS patients. Recruitment of patients into the study began in November 1996 and continued until December 1998. Both investigators have extensive experience in the administration of caudal epidural injections. The investigators and the patients were blinded to the treatment assignation. The active treatment group received 17 cc of normal saline, 3 cc of methylprednisolone acetate (40mg/cc, total = 120 mg) and 10 cc of a radio-contrast solution. Local anesthesia was used to position the needle in the sacrococcygian hiatus. Blind needle placement for caudal ESI is incorrect 25% to 38% of the time (Benson, 1986; Renfrew *et al.*, 1991; el-Khoury *et al.*, 1988), and even with ideal injection conditions (i.e. easily palpated sacral hiatus and high physician confidence in needle placement) the proportion of incorrect needle placement may be as high as 14% (95% confidence interval[CI] 6% - 27%) (Renfrew *et al.*, 1991). Therefore, fluoroscopy was used to guide and confirm the adequate localization of the injection. All patients were observed for 10 to 20 minutes following the technique, and all side effects or complications were recorded. In comparison, patients assigned to the placebo group received a similar caudal epidural injection following the same preparation and local anesthesia as used in the treatment group. Subjects in the control group received 20 cc of normal saline and 10 cc of a radio-contrast solution. The total volume injected was 30 cc in both groups.

Patients were evaluated at 1, 2, 3, 6 and 12 months after the initial injection. Clinical response and the patient's tolerance to therapy determined the frequency of the injections. The number of injections was limited to a maximum of six per year, with a minimum four-week interval between injections. At the randomization, patients' demographic, clinical, and medical history variables were collected and the LSS scales were used to assess patient's baseline symptom severity and physical function. At each

follow up visit (1, 2, 3, 6, and 12 months), the physical function and symptom severity scales, as well as the scale assessing patients' satisfaction with the treatment was administered with the aid and supervision of a trained research assistant.

4.1.1 Patient population

The study was open to both French-Canadian and English-Canadian patients. The validated English language LSS scales by Stucki *et al.* (1996) were used for English-Canadian patients while the French version was used in French-Canadian patients. All LSS patients were pre-selected by musculo-skeletal specialists (physiatrists, rheumatologists, orthopedic surgeons, and neurosurgeons) from three clinics of the Centre Hospitalier Universitaire de l'Université de Montréal (CHUM) and were aware of the inclusion and exclusion criteria. Subjects were consecutively screened for the study.

4.1.1.1 Inclusion criteria

1. Age greater than 45 years
2. Clinical criteria defining neurogenic claudication:
    - presence of pain in the low back or in one or both legs while walking or standing up
    - disappearance of pain or significant relief from sitting down for less than five minutes
    - little or no low back pain or leg pain at rest (sitting or lying down)
3. Radiographic confirmation of spinal canal narrowing (CT-scan, magnetic resonance imaging (MRI), epidurogram, myelography, showing area reduction, obstruction to distal flow of radio-contrast or cauda equina impingement).

Patients younger than 45 years of age were excluded to avoid the risk of over-representation of congenital LSS. There is no gold standard diagnostic criterion for symptomatic LSS; therefore, the opinion of clinicians and examiners served as a reference standard. This standardized and generalizable definition of LSS as a broad clinical syndrome has been successfully applied to identify candidates in studies of

surgical interventions and conservative therapies for LSS, conducted by Katz *et al.* (1995). At baseline, examiners confirmed the diagnosis and performed a standard physical examination. The examiners judged adequacy of the LSS diagnosis, the indication for surgery, the indication for ESI, and the potential for amelioration after the ESI (according to their clinical experience with the disease). All statements were rated on a scale ranging from 0-10, where 0 meant that the examiner totally disagreed, and 10 meant that the examiner perfectly agreed with the statement. The scores were used in the statistical analysis as potential response predictors and effect modifiers.

4.1.1.2 Exclusion criteria

Exclusion criteria included having coagulopathy or currently receiving anti-coagulant therapy; inability to complete questionnaires due to language or cognitive limitations; ESI in the last four months; history of spinal inflammatory disease; pregnancy; allergy to anesthetics, steroid compounds, or iodine. ESI have been given for the past 15 years at the Centre Hospitalier Universitaire de l'Universite de Montreal (CHUM) and the Institut de Physiatrie du Quebec based on a protocol discussed among experts in the field. Over 10,000 ESI have been given without any serious side effect or complication.

4.1.2 Ethical Considerations

The trial was approved by the Ethics Committee of the Hôpital Notre-Dame. English and French consent forms were used before patients were admitted to the study. Copies of the study approval and consent forms have been included in Appendix 1.

4.1.3 Randomization

Once eligibility had been established, informed consent was obtained and the patient was randomized to either a placebo injection or ESI treatment. To ensure optimal balance between the size of the two trial arms, blocked randomization, with blocks of six was used. Neither the treating physician nor the patient were informed of the treatment group assignment. The research assistant who assessed the patients was also blinded with respect to randomization.

4.1.4 Measures

At baseline, patient characteristics such as age, sex, education level, living status, socio-demographics, comorbid conditions, neuromuscular deficits, clinical history and symptoms inventory were derived from medical records. The following LSS-specific scales were used as primary outcome measures and completed by all patients at baseline, 1, 2, 3, 6, and 12 months: LSS symptom severity scale, LSS physical function scale, and LSS satisfaction scale. The secondary outcome measures included the Medical Outcomes Study (MOS) Short Form 36 item questionnaire (SF-36) (Ware, Jr. & Sherbourne, 1992), the Quebec Back Pain Disability Scale (Kopec *et al.*, 1995), the Visual Analog Scale (VAS) for pain experienced within last week, Modified Health Utilities Index --Mark III Scale (HUI-III) (Boyle *et al.*, 1995) and questionnaire on treatment expectations and preferences. Diagnostic imaging with CT-Scans or MRI was also performed at baseline.

At baseline, each patient underwent a physical examination where anthropometric measurements, evaluation of motor, sensory and reflex deficits, and straight leg raising tests were recorded on standardized forms by the examiners, who were also blinded to the treatment assignment. Examiners were also responsible for collecting information on clinical history such as history of spinal surgery, presence of neurogenic claudication, duration of symptoms, and cardiovascular co-morbidity.

Presence or absence of cardiovascular co-morbidity was assessed in order to identify patients at higher risk for vascular disease, which may confound clinical findings of neurogenic claudication. Data from medical records was collected on past and present occurrences of stroke, treated high blood pressure (HBP), diabetes, hypercholesterolemia or cardiac disease (i.e. previous angina, myocardial infarction, or cardiac surgery). Three variables were constructed based on these data. One variable represented history of cardiovascular disease (stroke or cardiac disease). Another indicated the presence of cardiovascular risk factors such as diabetes and/or hypercholestrolemia. Similar variables were grouped together because it was expected that there would be low prevalence of these variables individually, considering the low occurrence of these morbidities in the general population. The third variable was used to identify specifically those patients who had a history of treatment for HBP. This characteristic was looked at

by itself for two reasons. First, considering the epidemiology of HBP, it was expected that HBP would have a higher prevalence in the general population than other cardiac morbidities stated above. Second, HBP is a more generalized problem affecting the vascular system compared to cardiac events such as angina, cardiac surgery or myocardial infarction, which are more specific to the heart. Thus, because of the higher prevalence of HBP and because of its affect as a generalized vascular problem it was decided to consider HBP as a separate variable.

Patients were limited to the use of 1-2 tablets of Acetaminophen 325 mg every 4-6 hours, provided by the investigators. Regular pill counts were assessed at each visit. All referent attendings were informed of the participation of their patients, and were asked to limit pharmacological co-interventions to a strict minimum. Prescriptions of narcotics, or non-steroidal anti-inflammatory drugs (NSAIDs) were monitored for all study participants. Other measures that were recorded include: frequency of visits to physical or occupational therapy, use of heat or cold packs, exercises, back school, massage, corset use, transcutaneous electrical nerve stimulation (TENS), biofeedback, visits to other health practitioners (chiropractician, osteopath, or acupuncturist), and hospitalizations because of the LSS diagnosis.

English and French versions of all questionnaires are included in Appendix 2.

4.1.5 Follow-up Assessments

All patients were evaluated at 1, 2, 3, 6, and 12 months following the initial injection. At each time point patients were asked to fill in follow-up questionnaires with the aid and supervision of a trained research assistant. The same examiners who performed the initial examination provided a repeat medical and physical examination at each follow-up evaluation. The high number of follow-up visits aimed to limit the attrition of the study population and optimize assessment of the needs for re-injection. Re-injection was allowed up to 5 times over the 12-month follow-up period, with a minimum interval of 4 weeks between each procedure.

Clinical response and the patient's tolerance determined the frequency of re-injections. A standard definition of sub-optimal response lead to a discussion between the examiner and the patient on the indication of re-injection. A threshold of

improvement of 0.5 on either of the LSS scales (symptom severity or physical function) was used to trigger these discussions. If the improvement was > 0.5, the examiner did not recommend re-injection, unless the patient was not satisfied and preferred to have another injection. If the difference was ≤ 0.5. the examiner recommended another injection unless the patient was satisfied, or there was an adverse reaction, or the patient preferred not to have another injection. Such a strategy aimed to ensure a maximal therapeutic effect, while respecting patients' opinions.

Non-response after two injections was considered a 'treatment failure'. For the unresponsive patients, the code was broken immediately after the 3 months evaluation, to allow for re-assignation of the unresponsive patients in the placebo group to the active therapy. This assured that the assessment of outcomes at 3 months was still blinded with respect to treatment assignment. Follow-up visits in this specific sub-group were performed at 1, 3, and 9, months after this injection. Unresponsive individuals from the active therapy group were withdrawn, following the breaking of the code at 3 months. Otherwise, withdrawal was allowed at any time, upon patient request. Withdrawal was considered mandatory when there was progression of neurologic deficit. If a patient could not receive the injection through the sacrococcygeal hiatus, he/she was scheduled for lumbar epidural injection with follow-up visits at 1,3, 6, and 12 months after the injection. If a subject dropped out before 3-month follow-up, the patient was sent back to his attending physician.

4.1.6 Sample size calculation

Sample size and statistical power (Guyatt *et al.*, 1987) were estimated for the two principal outcomes, the LSS symptom severity and LSS physical function scales. Stucki *et al.* (1995) have suggested that minimal clinically important difference corresponds to the cutoff of 0.54 and 0.52, respectively, for the LSS symptom severity and physical function scales. The sample size estimation were carried out assuming the final outcomes will be analyzed using a 2-tailed t-test to test the null hypothesis of no differences between mean improvement in the two trial arms. Assuming a type I error of 0.05, a standard deviation of 0.52 for the symptom severity and 0.61 for the physical function scale (Stucki *et al.*, 1995), a sample size of 30 and 40 patients per group would yield a

power of 0.8 and 0.9, respectively, to detect the above minimal clinically important differences. (Table 4-1)

Under the above assumptions, a target of 40 patients per treatment group would ensure adequate statistical power and account for a 10% loss to follow-up at each subsequent follow-up visit (1, 3, 6, and 12 months). An alternative approach to sample size estimation takes into account an increase in precision due to adjustment for the covariates that have systematic effects on the outcomes. Assuming 20% of the variance being explained by the covariates, the residual standard deviation of the scales will be reduced, resulting in a reduction of the required sample size (Deyo *et al.*, 1991). For example, adjustment of the calculation according to this assumption would allow reduction of the sample size to 32 patients per treatment arm for the multivariable analyses. Thus, a conservative estimate of 40 patients per treatment group would allow for additional power. Moreover, the new approach proposed in this thesis, based on mixed models for longitudinal data (see section 4.3) would further enhance the power by making an efficient use of repeated outcome measurements.

TABLE 4-1: SAMPLE SIZE ESTIMATION FOR LSS SYMPTOM SEVERITY AND PHYSICAL FUNCTION SCALES

	Sample Size (per treatment arm)			
	0% loss to FU		With 34% loss to FU† at 12 months	
Statistical power	0.8	0.9	0.8	0.9
LSS Symptom Severity Scale	15	19	19	27
LSS Physical Function Scale	22	29	29	39

FU = Follow-up
LSS = Lumbar spinal stenosis
† Accounting 10% lost for each follow-up instance (1, 3, 6, 12 months)

4.2 Assessment of the psychometric properties of the French language LSS Scales

4.2.1 Introduction

The effectiveness of ESI in the randomized controlled trial will be assessed using mostly the French-translated versions of the LSS scales developed originally by Stucki *et al.* (1996). Thus, the measurement properties of the French language versions of the scales are essential for the valid interpretability of the trial results. Quality of measurement is usually described in terms of psychometric properties such as reliability and validity (Shrout, 1995). Both are fundamental criteria of good measurement. Reliability is the extent to which scores are reproducible under identical experimental conditions. Validity refers to the degree to which an instrument measures what it intends to measure. In addition, responsiveness to change, which is another important criterion for outcome measures, represents the ability of a measurement to detect clinically meaningful changes in instruments such as the LSS scales (Liang *et al.*, 1990; Fortin *et al.*, 1995). This section describes first the modifications and content of the French language LSS scales developed by Stucki *et al.* (1996). Then the statistical methods used to evaluate the psychometric properties of these instruments are presented. All analyses were conducted with SAS for personal computers (SAS version 6.12, SAS Institute, Cary, North Carolina).

4.2.2 Scale Development

Given the predominately French-Canadian population of the trial participants, all measures, including the spinal stenosis scales were administered in French. LSS scales developed by Stucki *et al.* (1996) were translated and adapted to a French-Canadian population using cross-cultural validation standards (Bullinger *et al.*, 1993; Guillemin *et al.*, 1993; Guyatt, 1993). English LSS scales were first translated into French from English by three different translators. Another three translators were then used to back-translate these versions into English to check for discrepancies. Discrepancies were then discussed with the translators before the final French version was adopted. Scales were pre-tested on patients with LSS to verify that questions were clear and understandable.

4.2.2.1 LSS Symptom severity scale

The symptom severity scale by Stucki *et al.* (1996) was used without modification. Areas assessed on the scale included overall pain, pain in the back, pain in legs, numbness, weakness, pain frequency, and problems with balance. Six out of the seven questions had Likert response scales with five categories scored 1-5 (none; mild; moderate; severe; very severe). Balance disturbance included three categories (none; sometimes; and often) and was scored on a 1-3-5 scale. An overall symptom severity score was calculated as an unweighted mean of the scores on individual items, if five or more questions were answered. Otherwise, if more than two responses were missing, overall score was not calculated for that patient. In accordance with Stucki *et al.* (1996), the symptom severity scale items were further classified into a pain and neuroischemic domain. The pain domain of the symptom severity scale included the three questions pertaining to overall pain severity, back pain, and pain frequency. The neuroischemic domain included the four questions of leg pain, weakness, numbness and balance disturbance. Unweighted mean scores for each of these domains was calculated if responses to at most one question in either domain was missing.

4.2.2.2 LSS Physical function scale

The physical function scale included five questions, which addressed patients' ability to walk a certain distance, ability to walk for pleasure, for groceries, around the home, and from bedroom to bathroom. The scale was slightly modified from Stucki *et al.* (1996), by including five instead of four categories, all in Likert response scale format with scores ranging from 1-5 (yes, without problem; yes, but with occasional pain; yes, but often with pain; yes, but always with pain; no, unable to do). The question assessing walking distance was also modified to five categories: over 2 miles (3 km); over 1 mile (1.5 km) but less than 2 miles (3 km); over 2 blocks but less than 1 mile (1.5 km); over 50 feet (15 meters) but less than 2 blocks; less than 50 feet (15 meters). Average scores for physical function were calculated as the unweighted mean of obtained individual scores, if four or more of the questions had been answered. Overall score was not calculated for those with more than one missing response.

4.2.2.3 LSS Satisfaction scale

The questionnaire discussing satisfaction was slightly rephrased and modified from the version used by Stucki *et al.* (1996) in their decompressive surgery trial. Changes were made so that the questionnaire was applicable to a study investigating the effectiveness of ESIs on LSS. Questions were asked about patient satisfaction with overall results of the injection, relief of numbness and tingling after injection, relief of pain after the injection, ability to walk comfortably, ability to do housework, yard work or job after the injection, strength in thighs, legs, or feet, and balance or steadiness in feet after injection. All questions had a Likert response format with scores ranging from 1-4, corresponding to, respectively, 'very satisfied', 'moderately satisfied', 'moderately dissatisfied', and 'very dissatisfied'. Satisfaction scale scores were calculated as the unweighted mean of all completed responses if more than five out of the seven questions were answered.

4.2.3 Statistical Analyses

4.2.3.1 Scale Characteristics

Scale score distributions were examined for normality and occurrence of floor and ceiling effects. The pair-wise associations between individual items of each LSS scale were assessed by Spearman's rank correlation coefficients, to identify possibly redundant pairs of items (correlation > 0.9). Item-to-item and item-to-total correlations were estimated at baseline for symptom severity and physical function scales, and at one month for the satisfaction scale. When estimating item-to-total correlations, the total was corrected by eliminating the respective item, so that association between an individual item and the total score of the other items in the scale could be assessed in an unbiased way (Streiner & Norman, 1995). An item-to-total correlation is considered adequate if it is above 0.4 (Cronbach, 1951).

4.2.3.2 Internal Consistency

For multi-item scales such as the LSS scale measures, it is important to evaluate how individual items relate to each other and to the total score. Referred to as internal consistency of the scale, this property is evaluated by Cronbach's alpha coefficient (Cronbach, 1951), which summarize the inter-item correlations for all items in a scale and may be conceptualized as the expected correlation between the actual scale and its hypothetical alternative version. Specifically, Cronbach's alpha is based on the average correlation of items in a scale if the items are standardized to have a standard deviation of one (Cronbach, 1951). Internal consistency of the LSS symptom severity and physical function scales was measured on the 79 French-Canadian patients at baseline, 1 and 3 months. The internal consistency of the satisfaction scale was also determined at 1 and 3 months.

4.2.3.3 Test-retest Reliability

An important property of good measurement is reliability. Scores observed on a measurement scale contain both real variations between subjects and error (Streiner & Norman, 1995). Reliability can be defined as the ratio of variance of the true score to the total variance of the observed score (Streiner & Norman, 1995). Clinicians must be certain that a difference in scores represents a true difference in the status of respective patients and not variation due to observers or random error (Streiner & Norman, 1995). *Inter-observer reliability* is concerned with the effect of different observers on the measurements of interest, while *intra-observer reliability* measures the variation within an observer in response to multiple exposures to the same stimulus (Streiner & Norman, 1995). When there are no observers involved in the measurement, the term used to determine its reliability is called *test-retest reliability* (Streiner & Norman, 1995). In this case, the goal is to administer the measure to be tested at two time points separated by an interval short enough that we can assume the scores and similarly the clinical state of the patient are unlikely to change (Streiner & Norman, 1995). Expert opinions vary on the appropriate length of this interval, but generally speaking, 2 to 14 days are considered acceptable (Streiner & Norman, 1995). Test-retest reliability was the reliability of concern in this thesis.

To assess test-retest reliability of the LSS symptom severity and physical function scales, retest data was initially collected via mailed questionnaires, which the patients filled on their own within two weeks of their initial visit. This method was rejected later because of concerns about systematic differences between the two assessments. The baseline data were collected with the aid of the research assistant and proved often essential to help the patients understand the questions and/or properly fill the responses. By contrast, at the retest time no such aid was available to patients. It was therefore, decided to redo the reliability study by ensuring similar conditions at test and retest times, within the time and financial constraints. In this second study, a copy of the questionnaire was provided to the patient to take home at the initial visit. The research assistant then telephoned a convenience sample of 40 patients at approximately two weeks after the initial visit, when responses to questions were obtained on both symptom severity and physical function scales. The latter study provided uniform help of the research assistant, either in person at the initial visit or on the telephone at retest time, and thus was expected to eliminate possible discrepancies due to patients' difficulty in filling the questionnaires.

Test-retest reliability of the overall score for each scale was measured by Pearson correlations and the intraclass correlation coefficient (ICC). Pearson correlations and 95% confidence intervals were calculated between scale scores at test and retest times. The ICC with one-sided lower limit of the 95% confidence limits were estimated using the formulae provided by Fleiss (1986) for the random effect model. Test-rest reliability was assessed using the convenience sample of 40 participants of the second study.

4.2.3.4 Validity

Reliability only determines whether an instrument is measuring something in a reproducible fashion, but does not state anything about what is actually being measured. Validity can be defined as the degree to which an instrument measures what it intends to measure (Streiner & Norman, 1995). Among different aspects of scale validity, content validity refers to whether individual items of the instrument adequately represent the area of interest. Content validity of the LSS scales has been addressed by Stucki *et al.* (1996), where questions used in the LSS scales were selected based on a literature review and

consensus of a panel of experts in LSS. Construct validity was assessed by generating hypotheses as to how the construct of the LSS symptom severity and physical function scales would correlate with established reliable and valid instruments measuring related constructs. These established constructs include the Quebec Back Pain Disability Scale (QBPDS) (Kopec *et al.*, 1995), mental and physical components of the MOS Short Form (SF-36) Scale (Ware, Jr. & Sherbourne, 1992; McHorney *et al.*, 1993), and the Visual Analog Scale (VAS) for pain. It was hypothesized that the physical function scale would correlate strongly with the physical component of the MOS SF-36 scale and the QBPDS. The symptom severity scale was hypothesized to correlate moderately with the overall physical component of the SF-36 and correlate moderately with the VAS pain scale. The pain domain of the symptom severity scale was hypothesized to correlate highly with the VAS pain scale because both are direct measures of pain. The pain domain was also hypothesized to correlate highly with the QBPDS since it is focused on determining disability due to back pain and, for obvious reasons, with the bodily pain component of the MOS SF-36. Validity was assessed using Pearson correlation coefficients. Patients requiring equipment such as canes or crutches were expected to have significantly higher scores on the physical function scale. This hypothesis was tested with a non-parametric Wilcoxon-rank-sum test, to account for the violation of the normality assumption due to the restricted range of scores.

The satisfaction scale was validated against separate responses to a question on whether the patient felt the injection(s) relieved pain, and to a question assessing whether the patient would choose to have the epidural injection if able to make the decision over again. These analyses relied on Spearman rank and Pearson correlation coefficients.

4.2.3.5 Responsiveness to change

Measuring sensitivity to change of the LSS scales is essential in assessing changes over time in a single group of patients and being able to discriminate, with respect to the amount and direction of change, between different groups of patients (Guyatt *et al.*, 1987) Responsiveness to change is also an essential property if the scale is used as an outcome measure in a randomized clinical trial or in a longitudinal study of the natural history of disease (Streiner & Norman, 1995). Conventional measures of responsiveness to change

include the standardized response mean (SRM) (Katz *et al.*, 1992; Liang *et al.*, 1990) and effect size (ES) (Kazis *et al.*, 1989). SRM is calculated as the ratio of the difference between mean instrument scores at two assessments, divided by the pooled standard deviation of the score differences. ES is defined as the difference in means divided by the pooled standard deviation of scores at baseline. However, when using these measures it is important to analyze patients who have really improved, separately from those whose status did not change (Fortin *et al.*, 2000). In fact, a responsive scale should yield high absolute values of SRM and ES for the group that truly improved and values close to 0 for the group that did not improve (Fortin *et al.*, 2000). In fact, since in our context a negative change in scale corresponds to improvement, the SRM and ES values should be negative for the improved group, while the values for the unimproved group may be slightly positive if some patients in this group actually became worse. In order to identify the two groups of patients, a general question about satisfaction, "Did the injection(s) in your spine relieve the pain?", was used as the external criterion for improvement. Patients who indicated that the injection either eliminated the 'pain entirely', 'almost all of the pain', or 'some of the pain' were considered to have improved whereas those patients who indicated no elimination of pain or pain worsening were considered not to have improved. Using this approach, separate analyses were conducted on responsiveness to change for the improved and not-improved groups. The responsiveness analyses assessed changes between baseline and, respectively, one and three months.

4.3 Statistical Analyses of the randomized controlled trial

Descriptive statistics including means and standard deviations for quantitative variables and proportions for categorical variables, were used to compare the two arms of the trial with respect to the distribution of the relevant characteristics and of the baseline values of the LSS scales and secondary outcome measures. The main analyses of the efficacy of the ESI treatment focused on the three first months after the first injection. Preliminary analyses involved testing of the unadjusted difference between mean improvements from the baseline in the ESI and placebo groups, using two-tailed independent groups t-tests separately at 1, 2 and 3 months of follow-up.

To increase statistical power and to reduce concerns due to multiple testing, the primary analyses relied on the joint analysis of the outcomes observed at the three evaluations. To account for the dependence of the subsequent results for the same patient, this was achieved with mixed models for the unbalanced multivariable repeated measures analysis of variance (Jennrich & Schluchter, 1986). The additional advantages of this approach are that it allows for varying number of observations per patient as well as for the inclusion of both fixed-in-time, between-patients variables, such as baseline characteristics, and of time-dependent variables such as time of evaluation or its interaction with treatment. To gain full insight into the effects of treatment, a series of mixed repeated measures models of different complexity were estimated for each outcome. In all models, the scores of the relevant outcome (e.g. LSS scale) at the three visits represented repeated measurements of the dependent variable. All models included at least two essential independent variables: a binary indicator of the treatment group and the baseline score of the scale used as the outcome in a given analysis. Initial models focused on the homogeneity of results across the three evaluations and allowed testing statistical significance of the linear trend over time and of the time-by-treatment interaction. The test of this interaction was essential as its results determined the strategy of further analyses. A statistically significant interaction, at $\alpha = 0.05$, was interpreted as an evidence that the treatment effect varies systematically between the three evaluation times. In that case, further analyses were conducted separately for each of the three months, using conventional multiple linear regression, as the month-specific analyses did not involve repeated measures. By contrast, the absence of a statistical significant treatment-by-time interaction was considered as an evidence of the homogeneity of the treatment effect across the three months. In either case, the second step of the analyses involved multivariable modeling in which treatment effect was further adjusted for the following *a priori* selected set of covariates: age, sex, duration of neurogenic claudication, secondary or post-secondary education, physician confidence in the LSS diagnosis, and presence of cardiovascular co-morbidity. Final multivariable analyses aimed at testing if the treatment effect depended on some of the relevant covariates. This was achieved by adding one treatment-by-covariate interaction at a time to the multivariable model with all covariates, and testing its statistical significance. At this

stage of the analyses, the more stringent significance level of 0.01 was employed to account for inflated type I error risk, due to multiple testing. In the case of a significant interaction, separate analyses of treatment efficacy were carried out for the subgroups of patients corresponding to different values of the covariate. The above approach was used for each of the primary and secondary outcome measures.

A similar approach was employed to analyze outcomes at 6 and 12 months after the first injection, except for two modifications. First, it was *a priori* decided that there is no substantive ground to expect that the treatment effect observed over the first 3 months, corresponding to the main horizon for efficacy analyses according to the original protocol, would remain constant at 6 and/or 12 months. Second, the sample size at 6 months was markedly smaller than at 3 months and at 12 months it had decreased below 50% of the original trial participants. For these reasons, the outcomes for 3 months and for 6 or 12 months were analyzed in two separate analyses, with only one observation per patient, which allowed the use of conventional multiple linear regression. The sample size considerations required also that the number of covariates in the multivariable models be reduced, to meet the minimum of 5 observations per independent variable in the model. Therefore, the multiple linear regression models for 6 and 12 months included, in addition to the relevant baseline score, only those covariates that had statistically significant effects in the repeated measures analyses of the first 3 months.

Unless otherwise specified, a significance level of 0.05 was used for all hypothesis testing. Analyses were conducted with the statistical package SAS for personal computers (SAS version 6.12, SAS Institute, Cary, North Carolina). Procedure MIXED was used for repeated measures analyses and procedure GLM / REG for multiple linear regression.

CHAPTER 5: RESULTS

5.1 Study population

During the recruitment phase of the trial, November 1996 to December 1998, the investigators screened a total of 125 patients. Thirty-two patients (25.6%) were excluded based on *a priori* exclusion criteria and eight patients (6.4%) refused to participate in the study. Of the 85 remaining patients enrolled in the study, 42 patients were randomized to the treatment group and 43 to the control group. Of these randomized patients, four were excluded from the study because the volume could not be injected through the sacrococcygian hiatus. Another patient was initially enrolled but excluded because the volume that was injected penetrated the subarachnoid space. Of the five patients who could not be injected, four were initially randomized into the treatment group and one into the control group. Thus, follow-up over the one year period was done on the remaining 80 randomized patients, of which 38 were from the treatment group and 42 from the control group (Table 5-1). There were no drop-outs and no subject was lost to follow-up at 3 months. At six months, 45 patients remained randomized. The code had been opened for 35 of the patients at six months because they were not experiencing a positive effect from the injections. At six months, 12 of these patients came from the treatment group and 23 came from the control group. At 12 months the code had been broken for 51 patients on similar grounds, therefore leaving 29 patients still randomized.

5.1.1 Baseline Characteristics for entire sample

Distributions of demographic and clinical variables at the baseline visit for the two trial arms are compared in Table 5-2. Patients enrolled in the study were followed for an average of 6.9 ± 4.1 months (range, 3 to 12). The mean age was 68.2 years (median = 68 years, range 49-91) and 55% were women. The median number of injections per patient was 2 (range 1-3). Over one year, more than 200 caudal epidural injections were given to the 80 subjects. There were no reports of serious side effects by any of the patients. Fourteen percent of patients were working (28.6% of the patients under 65), 38.8% had high school or post-secondary level education, and 30% lived alone. Patients in the two groups have very similar values for most relevant variables,

TABLE 5-1: ELIGIBILITY AND ENROLLMENT

		Number
Total number assessed by the investigators		125
Number of patients excluded		40
Refused to participate	8	
No neurogenic claudication	26	
No spinal stenosis on CT or MRI	4	
History of spinal inflammatory disease	1	
Allergy to iodine	1	
Number of patients initially randomized		85
Treatment group	42	
Control group	43	
Number of randomized patients who were successfully injected		80
Treatment group	38	
Control group	42	

TABLE 5-2: BASELINE DEMOGRAPHIC AND PATIENT CHARACTERISTICS FOR CONTROL AND TREATMENT GROUPS (N=80)

	Treatment (n=38)	**Control (n=42)**
	Mean (SD) *Number (%)*	**Mean (SD)** *Number (%)*
Age (years)	**69.3 (8.4)**	**67.0 (8.7)**
Race		
White	37 (97.4)	41 (97.6)
Black	1 (2.6)	1 (2.4)
Gender		
Male	15 (39.5)	21 (50.0)
Female	23 (60.5)	21 (50.0)
Education		
Number of years	**9.0 (4.5)**	**10.7 (4.9)**
Completed high school or higher	13 (34.2)	18 (42.9)
Number of Medications currently taken	**4.4 (2.9)**	**3.5 (2.7)**
Living Alone	9 (23.7)	15 (35.7)
Currently working	6 (15.8)	5 (11.9)
Use of Cane or Crutch	8 (21.0)	9 (21.4)
Cardiovascular Morbidity Present (at least one of the following five conditions present)	27 (71.1)	24 (57.1)
Stroke	4 (10.5)	1 (2.4)
High Blood Pressure	18 (47.4)	13 (31.0)
Heart Disease	7 (18.4)	8 (19.1)
Hypercholesterolemia	3 (7.9)	7 (16.7)
Diabetes	3 (7.9)	6 (14.3)
Symptom Duration (months)		
Back Pain	**70 (76)**	**71 (80)**
Neurogenic claudication	**35 (31)**	**31 (33)**
Leg Pain	**32 (30)**	**30 (33)**

SD: standard deviation

although those in the treatment group included fewer males, were somewhat less educated and had higher prevalence of high blood pressure.

Cardiovascular co-morbidity was present in 63.8% of patients. Thirty-nine percent of patients were currently being treated for high blood pressure. Ten patients were at risk for hypercholesterolemia and 9 patients suffered from diabetes. Only three patients had a history of heart attack, 5 patients had experienced a stroke, and 6 patients had undergone cardiac surgery.

Median duration of symptoms was 36 months, and 17% had duration under 12 months. The median duration of specific symptoms of neurogenic claudication was 24 months; 22% had exhibited symptoms of neurogenic claudication for longer than 36 months, 20% had only had neurogenic claudication for less than 12 months. Duration of leg pain ranged from 0-180 months, with a median of 24 months.

Distributions of baseline responses to individual items on the symptom severity and physical function scales are shown in Tables 5-3 and 5-4, respectively. Every three out of four patients experienced severe or very severe pain, about one half had severe or very severe leg pain, and almost all (97.5%) experienced daily pain. More than half of the patients experienced balance disturbance, 58.7% weakness, and 62.5% numbness or tingling. About half of the patients were severely limited in their functional ability and were not able to walk more than two blocks. Half of the patients were not able to take walks for pleasure without always experiencing pain. One out of every five patients were not able to walk for pleasure at all. Shopping for groceries was not possible without always experiencing pain for about one half of patients. Every fourth patient required another person to miss work to accompany them to their treatments, to visit the doctor, or to have medical tests done because of their back problem.

Table 5-5 compares distributions of LSS scale scores at baseline in the two trial arms. As expected, the two distributions are quite similar, although the patients in the treatment group had slightly higher initial symptom severity and physical function scale scores. Overall, the total scores of the symptom severity scale at baseline ranged from 2 to 5 (possible range, 1-5), with mean 3.1 and standard deviation of 0.6. These scores displayed a relatively symmetric, almost normal distribution. The total scores of the physical function scale at baseline ranged from 1.4 to 4.6 (possible range, 1-5), with

TABLE 5-3: DISTRIBUTION OF RESPONSES ON INDIVIDUAL ITEMS OF THE SYMPTOM SEVERITY SCALE AT BASELINE* (N = 80)

In the Last Month, How Would you Describe:	No.	%
1. The pain you have had on average including pain in your back, buttocks and pain that goes down the legs?		
None	0	0
Mild	1	1.3
Moderate	19	23.8
Severe	44	55.0
Very severe	16	20.0
2. The pain in your back or buttocks?		
None	3	3.8
Mild	4	5.0
Moderate	26	32.5
Severe	36	45.0
Very severe	11	13.8
3. The pain in your legs or feet?		
None	5	6.3
Mild	14	17.5
Moderate	19	23.8
Severe	30	37.5
Very severe	12	15.0
4. Numbness or tingling in your legs and feet?		
None	30	37.5
Mild	15	18.8
Moderate	19	23.8
Severe	13	16.3
Very severe	3	3.8
5. Weakness in you legs or feet?		
None	33	41.3
Mild	14	17.5
Moderate	23	28.8
Severe	6	7.5
Very severe	4	5.0
6. How often have you had back, buttock, or leg pain?		
Less than once a week	0	0
At least once a week	2	2.5
Everyday, for at least a few minutes	19	23.8
Everyday, for most of day	46	57.5
Every minute of the day	13	16.3
7. The problems with your balance?		
No, I've had no problems with my balance	37	46.3
Yes, sometimes I feel my balance is off, or that I am not sure-footed	34	42.5
Yes, often, I feel my balance is off, or that I am not sure-footed	9	11.3

* The items are presented as they have been used in the questionnaire. Questions 1, 2, and 6 represent the pain domain (severity, back pain, and frequency), while questions 3,4,5 and 7 represent the neuroischemic domain (leg pain, weakness, numbness, and balance disturbance)

TABLE 5-4: DISTRIBUTION OF RESPONSES ON INDIVIDUAL ITEMS OF THE PHYSICAL FUNCTION SCALE AT BASELINE* (N = 80)

In the Last Month, on a Typical Day:	No.	%
1. How far have you been able to walk?		
Over 2 miles (3 km)	3	3.8
Over 1 mile (1.5 km) but less than 2 miles (3 km) †	4	5.0
Over 2 blocks, but less than 1 mile (1.5 km) ‡	30	37.5
Over 50 feet (15 meters) but less than 2 blocks	33	41.3
Less than 50 feet (15 meters)	10	12.5
2. Have you taken walks outdoors or in malls for pleasure?		
Yes, comfortably	1	1.3
Yes, but with occasional pain §	9	11.3
Yes, but often with pain ¶	12	15.0
Yes, but always with pain	41	51.3
No, unable to do	17	21.3
3. Have you been shopping for groceries or other items?		
Yes, comfortably	2	2.5
Yes, but with occasional pain §	9	11.4
Yes, but often with pain ¶	18	22.8
Yes, but always with pain	40	50.6
No, unable to do	10	12.7
4. Have you walked around the different rooms in your house or apartment?		
Yes, comfortably	31	38.8
Yes, but with occasional pain §	20	25.0
Yes, but often with pain ¶	14	17.5
Yes, but always with pain	15	18.8
No, unable to do	0	0
5. Have you walked from you bedroom to the bathroom?		
Yes, comfortably	36	45.0
Yes, but with occasional pain §	22	27.5
Yes, but often with pain ¶	7	8.8
Yes, but always with pain	15	18.8
No, unable to do	0	0

* The items are presented as they have been used in the questionnaire.

†, ‡ These two categories replaced the option "Over 2 blocks, but less than 2 miles" from the original version of the Physical Function Scale by Stucki *et al.* (1996)

§, ¶ The original version of the Physical Function Scale by Stucki *et al.* (1996) only included the option "Yes, but sometimes with pain", whereas this version has been modified to include two options "Yes, but with occasional pain" and "Yes, but often with pain".

TABLE 5-5: OVERALL BASELINE SCORES ON SPECIFIC SCALES FOR CONTROL AND TREATMENT GROUPS (N=80)

	Treatment (n=38)	Control (n=42)
	Mean (SD) *Number (%)*	**Mean (SD)** *Number (%)*
Overall Mean Scores		
LSS Symptom Severity Scale (1-5)	**3.2 (0.5)**	**2.9 (0.6)**
Neuroischemic domain (1-5)	**2.7 (0.8)**	**2.4 (0.8)**
Pain domain (1-5)	**3.9 (0.5)**	**3.7 (0.7)**
LSS Physical Functional Scale (1-5)	**3.2 (0.8)**	**2.8 (0.7)**
Quebec Back Pain Disability Scale (0-10)	**3.9 (1.4)**	**4.0 (1.7)**
MOS SF-36 Scale – Physical Component	**30 (8)**	**30 (9)**
MOS SF-36 Scale – Mental Component	**56 (10)**	**52 (12)**
VAS Pain Scale (pain in last week, 0-10)	**7.4 (1.7)**	**7.0 (2.1)**
Physician Confidence (scale score 0-10)		
LSS Diagnosis	**8.5 (0.7)**	**8.3 (0.9)**
ESI benefit	**5.8 (1.0)**	**5.9 (1.0)**

LSS: lumbar spinal stenosis;
MOS SF-36: Medical Outcomes Study Short Form 36;
VAS: Visual Analog Scale;
ESI: epidural steroid injection
SD: standard deviation

mean 3.0 and standard deviation of 0.8. These scores also displayed a near normal distribution. Neither scale displayed clustering at scale extremes, thus ruling out floor or ceiling effects.

5.1.2 One and three month characteristics of the LSS satisfaction Scale

Distributions of one and three month responses on the LSS satisfaction scale are shown in Table 5-6. Although satisfaction scores reflect the outcomes of the intervention rather than the baseline characteristics of the study population, I report their distribution here to facilitate reading of the next section that focuses on the psychometric properties of all LSS scales, including the satisfaction scale. About 2 out of every 3 patients were at least moderately satisfied with the overall results of the injection at both one and three months. More than half of patients were either moderately or very satisfied with the relief of their pain, numbness and tingling at both one and three months. Half of patients reported to be at least moderately satisfied with the strength in their thighs, legs and feet at one month. Less than half of patients were satisfied with their balance or steadiness on their feet at one month, although this increased to more than half by three months.

TABLE 5-6: DISTRIBUTION OF RESPONSES ON INDIVIDUAL ITEMS OF THE SATISFACTION SCALE AT 1 MONTH AND 3 MONTH FOLLOW-UP.*

How Satisfied Are You With:	1 Month		3 Month	
	No.	%	No.	%
1. The overall results of the injection?				
Very satisfied	19	24.4	23	29.9
Moderately satisfied	34	43.6	26	33.8
Moderately dissatisfied	13	16.7	14	18.2
Very dissatisfied	12	15.4	14	18.2
2. The relief of your numbness and tingling?				
Very satisfied	21	33.3	19	30.6
Moderately satisfied	15	23.8	15	24.2
Moderately dissatisfied	16	25.4	19	30.6
Very dissatisfied	11	17.5	9	14.5
3. The relief of your pain?				
Very satisfied	17	21.5	18	23.4
Moderately satisfied	32	40.5	26	33.8
Moderately dissatisfied	18	22.8	21	27.3
Very dissatisfied	12	15.2	12	15.6
4. Your ability to walk comfortably?				
Very satisfied	16	20.3	20	26.0
Moderately satisfied	28	35.4	27	35.1
Moderately dissatisfied	20	25.3	16	20.8
Very dissatisfied	15	19.0	14	18.2
5. Your ability to do housework, yard work, or your job?				
Very satisfied	16	20.8	20	26.0
Moderately satisfied	28	36.4	26	33.8
Moderately dissatisfied	22	28.6	18	23.4
Very dissatisfied	11	14.3	13	16.9
6. Your strength in the thighs, legs and feet?				
Very satisfied	15	24.2	12	18.5
Moderately satisfied	16	25.8	22	33.8
Moderately dissatisfied	21	33.9	18	27.7
Very dissatisfied	10	16.1	13	20.0
7. Your balance or steadiness on your feet?				
Very satisfied	8	15.7	10	18.9
Moderately satisfied	13	25.5	18	34.0
Moderately dissatisfied	23	45.1	16	30.2
Very dissatisfied	7	13.7	9	17.0

*The items are presented as they have been used in the questionnaire.

5.2 Psychometric properties of the French language LSS Scales

5.2.1 Introduction

The following section reports the results of a sub-study focusing on the psychometric properties of the French translated LSS scales and involving 79 of the original 80 patients included in the study. One patient was English-Canadian and filled the English versions of the questionnaires. This patient was excluded from this sub-study on French-Canadian patients.

5.2.2 Scale Characteristics

Item-item correlations within the pain domain of the symptom severity scale were all positive and statistically significant ($p < 0.05$) and ranged from 0.31 (overall pain and pain frequency) to 0.69 (overall pain and back pain). Correlations within the neuroischemic domain were weaker but also statistically significant ($p<0.05$) except for correlation of leg pain and balance ($r = 0.14$, $p=0.20$). Other correlations ranged from 0.23 (leg pain and weakness) to 0.34 (numbness or tingling and balance). All item-item correlations within the physical function scale were statistically significant ($p<0.05$) and ranged from 0.28 (walking outdoors for pleasure and walking in home) to 0.93 (walking in home and walking from bed to bath). All inter-item correlations for the satisfaction scale at one month were high and statistically very significant ($p < 0.0001$) and ranged from 0.66 (satisfaction with relief of numbness/tingling and balance) to 0.91 (satisfaction with pain relief and overall results of ESI).

Item-total correlations ranged from 0.19 (pain frequency) to 0.52 (overall pain) for the symptom severity scale. For the physical function scale, item-total correlations were generally higher and ranged from 0.57 (walking distance) to 0.73 (walks for groceries) (Table 5-7). Thus, each item within the symptom severity and physical function scales did contribute a substantial portion of unique information., while at the same time, all items appeared to well represent the same general domain. By contrast,

TABLE 5-7: ITEM TO TOTAL CORRELATIONS FOR SYMPTOM SEVERITY AND PHYSICAL FUNCTION SCALES AT BASELINE (N=79)

Item	Pearson Correlation with total*
Symptom Severity Scale	
1. Overall Pain	0.52
2. Pain in the Back	0.36
3. Pain in Legs or Feet	0.35
4. Numbness	0.39
5. Weakness	0.32
6. Pain Frequency	0.19
7. Problems with Balance	0.32
Physical Function Scale	
1. Walking Distance	0.57
2. Walks for Pleasure	0.62
3. Walks for Groceries	0.73
4. Walks in House or Apartment	0.62
5. Walks from Bedroom to Bathroom	0.70

* Total is the total score for that particular scale with the given item deleted

individual items on the satisfaction scale were somewhat redundant, as at one month, item-total correlations ranged from 0.80 (relief of numbness and tingling) to 0.95 (pain relief).

5.2.3 Internal Consistency

As expected, based on moderate to high item-item correlations, the internal consistency of the scales at baseline (N=79) was satisfactory to very good and ranged from Cronbach's α of 0.66 for the symptom severity scale to 0.84 for the physical function scale (Table 5-8). By three months, the internal consistency of both symptom severity and physical function had increased to 0.82 and 0.90, respectively. At both one and three months the satisfaction scale displayed a very high internal consistency (Cronbach's $\alpha = 0.97$).

5.2.4 Test-retest Reliability

The assessment of the test-retest reliability of the baseline scores of the physical function and symptom severity scales was carried out using a convenience sample of 40 patients. The median time interval between test and retest times was 13 days (range, 8-16 days). All individual items showed at least satisfactory test-retest reliability as Pearson correlation coefficients ranged from 0.53 (back pain) to 0.76 (leg pain) for the symptom severity scale and from 0.71 (walks from bed to bath, walks around different rooms in home) to 0.95 (walking distance) for the physical function scale. Pearson correlation coefficients ranged from 0.79 for the pain domain of the symptom severity scale to 0.91 for the physical function scale (Table 5-9). Intraclass correlation coefficients based on the test-retest data for the symptom severity and physical function scales were 0.87 and 0.91, respectively, indicating excellent test-retest reliability. Lower limits of the 95% confidence interval for these ICCs were 0.79 for symptom severity and 0.87 for physical function. Table 5-9 also shows that for all scales the mean scores at test and retest were quite similar, indicating the absence of any systematic shift in scores. The LSS satisfaction scale was not re-tested, as it was not administered at the initial visit.

TABLE 5-8: INTERNAL CONSISTENCY OF SYMPTOM SEVERITY, PHYSICAL FUNCTION, SATISFACTION, PHYSICAL COMPONENT OF THE SF-36, AND QUEBEC BACK PAIN DISABILITY SCALES AT BASELINE, 1, AND 3 MONTHS (N=79)

	Cronbach's α Coefficient		
Scale	**Baseline**	**One Month**	**Three Months**
Symptom Severity Scale	0.66	0.82	0.82
Pain domain	0.69	0.81	0.87
Neuroischemic domain	0.58	0.74	0.69
Physical Function Scale	0.84	0.87	0.90
Satisfaction Scale	NA	0.97	0.97
SF-36 (Physical Component)	0.60	0.56	0.63
Quebec Back Pain Disability Scale	0.91	0.92	0.93

NA = not applicable

TABLE 5-9: TEST-RETEST RELIABILITY OF SYMPTOM SEVERITY AND PHYSICAL FUNCTION SCALES

	Test	Re-test	Test- Retest Reliability (N=40)	
Scale	**Mean (SD)**	**Mean (SD)**	**ICC (LLCI)**	**Pearson Correlation* (CI)**
Symptom Severity Scale	3.01 (0.76)	2.89 (0.74)	0.87 (0.79)	0.88 (0.78 – 0.93)
Pain domain	3.56 (0.88)	3.48 (0.80)	0.79 (0.67)	0.79 (0.63 – 0.88)
Neuroischemic domain	2.59 (0.91)	2.44 (0.88)	0.84 (0.74)	0.85 (0.73 – 0.92)
Physical Function Scale	3.11 (1.14)	3.06 (1.11)	0.91 (0.87)	0.92 (0.85 – 0.96)

SD = standard deviation
CI = 95% confidence interval
ICC = intraclass correlation coefficient
LLCI = lower limit of the 95% confidence interval
*All Pearson correlations statistically significant (P < 0.0001)

5.2.5 Validity

As hypothesized, the LSS physical function scale was strongly correlated with both the physical components of the SF-36 and the QBPDS (Table 5-10). No significant correlation was seen between the physical function scale and the mental component of the SF-36. As expected, patients using assistive devices such as canes or crutches had a significantly higher physical function disability score than those not using such devices (3.3 vs. 2.9, $p < 0.05$).

The symptom severity scale was strongly correlated with the QBPDS and moderately correlated with both the pain measured by the visual analog scale and physical component of the SF-36 (Table 5-10). A weak but statistically significant correlation was found between the symptom severity scale and the mental component of the SF-36. The pain domain was strongly correlated with both the physical component ($r = 0.46$; 95% CI, 0.26 to 0.62) and bodily pain component of the SF-36 ($r = 0.59$; 95% CI, 0.42 to 0.71), but not correlated with the mental component ($r = 0.16$; 95% CI, -0.08 to 0.38; $p = 0.20$). As hypothesized, the pain domain was also highly correlated with pain measured by the visual analog scale and the QBPDS. The neuroischemic domain was weakly correlated with the SF-36 mental component and with the QBPDS.

The satisfaction scale score was validated against a question on whether patients would have elected to have a ESI if able to make the decision over again. Table 5-11 shows that at one month there was little difference in satisfaction scores between patients who answered 'yes' and 'no' to this question ($p=0.16$). However, at three months, patients who would have chosen ESI again had a satisfaction scale score of 2.1, which is significantly better than 3.4, the mean score for those who would not have elected an ESI again ($p < 0.0001$). A question about patient's pain relief had a strong association with the LSS satisfaction scale score at one and three months. Those that felt the ESI relieved their pain had a mean satisfaction score of 1.9 at three months, which was significantly better than 3.1, the mean of those not relieved of pain ($p < 0.0001$). (Table 5-11)

TABLE 5-10: ASSESSMENT OF THE CONCURRENT VALIDITY OF THE PHYSICAL FUNCTION AND SYMPTOM SEVERITY SCALES AGAINST THE PHYSICAL AND MENTAL COMPONENTS OF THE MOS SHORT FORM (SF-36) SCALE, QUEBEC BACK PAIN DISABILITY SCALE (QBPDS) AND PAIN AS MEASURED WITH A VISUAL ANALOGUE SCALE (VAS) AT BASELINE

	Pearson correlation coefficients (95% confidence limits)			
	SF-36		QBPDS	VAS
	Physical	Mental		
Physical Function Scale	0.61* (0.43-0.73)	0.22 (-0.01-0.44)	0.59* (0.42-0.71)	0.33† (0.12-0.52)
Symptom Severity Scale	0.33† (0.10-0.53)	0.26‡ (0.02-0.47)	0.50* (0.32-0.65)	0.39¶ (0.18-0.56)
Pain domain	0.46* (0.26-0.62)	0.16 (-0.08-0.38)	0.60* (0.44-0.72)	0.55* (0.38-0.69)
Neuroischemic domain	0.13 (-0.11-0.35)	0.24‡ (0.01-0.45)	0.31† (0.09-0.49)	0.18 (-0.04-0.39)

* $P < 0.0001$
¶ $P < 0.001$
† $P < 0.01$
‡ $P < 0.05$

TABLE 5-11: VALIDATION OF THE SATISFACTION SCALE AGAINST PATIENTS' RESPONSES REGARDING EFFECTIVENESS OF EPIDURAL STEROID INJECTIONS

	Mean Satisfaction Scale Score[a]					
	1 month			3 months		
Question	Yes	No	p-value*	Yes	No	p-value*
1. Did the injection(s) in your spine relieve the pain?	1.8	3.4	< 0.0001	1.9	3.1	< 0.0001
2. Now that you have learned a lot about injections for spinal stenosis, if you could go back in time, would you choose to have the back injection again?	2.3	2.7	0.1553	2.1	3.4	< 0.0001

* The Wilcoxon rank sum test was used to compare the mean rank on the satisfaction scale in those who said 'yes' and those who said 'no', for each question.

(a) A lower score on the LSS satisfaction scale indicates a more satisfied patient.

5.2.6 Responsiveness to change

To assess the responsiveness to change of LSS symptom severity and physical function scales, the question about satisfaction was used as an external criterion to discriminate between patients who were considered to have improved and those who were not. Change in the overall symptom severity scale was moderately correlated with the satisfaction scale at each visit, with correlations ranging from 0.34 at three months to 0.49 at one month (Table 5-12). Likewise, the mean change in the physical function scale was moderately correlated with the satisfaction scale scores, ranging from 0.43 at one month to 0.45 at three months. Satisfaction was moderately correlated with change in pain and neuroischemic domains at one and three months except for the change in neuroischemic domain score at three months, where the correlation was found to be weak ($r = 0.23$; 95% CI, 0.00 to 0.44) (Table 5-12).

As expected, the values of both measures of responsiveness to change, ES and SRM were substantially higher in satisfied patients compared to unsatisfied patients (Table 5-13). A negative mean change in the instrument score indicated an improvement in symptom severity or function ('1', no pain/able to do comfortably to '5', severe pain/unable to do) between baseline and specific month (i.e. 1 or 3 months). For satisfied patients at one month, both the symptom severity scale and the physical function scale were moderately responsive. Using patients' satisfaction as the external criterion for 'true' change, the pain domain was found to be more responsive than the neuroischemic domain at one and three months. At three months, responsiveness of both the symptom severity and physical function scales was lower than determined at one month, but the values remained meaningfully different from the unsatisfied group.

TABLE 5-12: CORRELATION BETWEEN CHANGES IN THE LSS SYMPTOM SEVERITY AND PHYSICAL FUNCTION SCALES AND THE SATISFACTION SCALE

Scale Score Improvements from Baseline	Pearson correlation coefficients (95% confidence limit)	
	Satisfaction Scale Score	
	1 month	3 months
Symptom Severity Score Difference	0.49* (0.29-0.65)	0.34† (0.11-0.53)
Pain Domain Score Difference	0.41¶ (0.20-0.59)	0.37† (0.15-0.56)
Neuroischemic Domain Score Difference	0.46* (0.25-0.63)	0.23 (0 - 0.44)
Physical Function Score Difference	0.43¶ (0.22-0.60)	0.45* (0.24-0.62)

* $P < 0.0001$
¶ $P < 0.001$
† $P < 0.01$
‡ $P < 0.05$

TABLE 5-13: RESPONSIVENESS OF THE LSS SYMPTOM SEVERITY AND PHYSICAL FUNCTION SCALES AS ASSESSED BY STANDARDIZED RESPONSE MEAN (SRM) AND EFFECT SIZE (ES) AMONG SATISFIED AND UNSATISFIED PATIENTS AT 1 AND 3 MONTHS.

	Responsiveness							
	Satisfied Patients[a]				Unsatisfied Patients[b]			
	SRM		ES		SRM		ES	
Months	1	3	1	3	1	3	1	3
Number	50	51	50	51	26	27	26	27
Symptom severity scale	-0.63	-0.38	-0.92	-0.52	0.12	-0.03	0.10	-0.02
Pain domain	-0.79	-0.56	-1.13	-0.77	-0.02	0.05	-0.02	0.06
Neuroischemic domain	-0.43	-0.17	-0.53	-0.21	0.17	-0.07	0.15	-0.06
Physical function scale	-0.57	-0.29	-0.54	-0.36	0.10	0.08	0.08	0.07

[a] Satisfied patients defined as those who indicated pain improvement, when asked the question "Did the injection in your spine RELIEVE the PAIN?

[b] Unsatisfied patients defined as those who indicated no improvement or worse pain, when asked the question "Did the injection in your spine RELIEVE the PAIN?

Please see methods section 5.2.6 for explanation.

SRM = Standardized response mean
ES = Effect size

5.2.7 Summary of results for the LSS scales evaluation

The French language versions of the spinal stenosis scale instruments demonstrated high test-retest reliability and high internal consistency. The LSS symptom severity and physical function scales were significantly correlated with established scales such as the Quebec Back Pain Disability Scale and the physical component of the SF-36 scale, indicating strong evidence for construct validity. By using patient responses related to their satisfaction as an external criterion of change, the LSS symptom severity and physical function scales were shown to highly discriminate between those satisfied and unsatisfied, demonstrating that these outcomes are responsive to change.

The overall performance of the French-translated LSS scales makes them useful, valid and reliable measures of outcomes for the randomized controlled trial, the results of which are reported in the next section.

5.3 Results of the randomized controlled trial

5.3.1 Results for the first three months of follow-up – Primary outcome measures

Baseline characteristics of the two groups were compared in Tables 5-2 and 5-5 in Section 5.1.1. Patients in the ESI and placebo groups had similar values for most relevant characteristics, but there was a trend towards higher severity in the ESI group.

Table 5-14 compares the distribution of changes in LSS symptom severity and physical function scale scores in the two trial arms, separately at 1, 2, and 3 months of follow-up. At one month, an improvement of 0.54 points was found from baseline on the LSS symptom severity scale for the ESI group, versus only a 0.06 improvement in the placebo group. These improvements were found to be statistically significantly different ($p=0.0076$). A similar pattern of results at one month was seen in both ESI and placebo groups on the LSS physical function scale, with improvements between groups found to be statistically significantly different ($p=0.0018$). At two months, score improvements for ESI and placebo groups were not significantly different on either the symptom severity or physical function scale, although there was a trend for greater improvement in the ESI group over the placebo group for both scales. In the treatment group, improvement in physical function was sustained at two months, while improvement in symptom severity tended to be slightly lower compared to one month. At three months, improvements from baseline in ESI and placebo groups were not statistically significantly different for symptom severity ($p=0.0731$) or physical function scales ($p=0.3731$). Nevertheless, there was a continued trend of greater improvement in the ESI group compared to placebo, although the improvement was not as great as at one or two months.

However, the interpretation of the results presented in Table 5-14 should be examined with care, for two reasons. First, the comparison does not take into account a moderate difference in the distribution of the baseline scores in the two groups (see Table 5-5, Section 5.1.1). Given that, due to the regression to the mean phenomenon, patients with higher initial severity may tend to improve more, this creates a risk of some confounding by baseline severity. Second, the comparison is less conclusive due to

TABLE 5-14: DISTRIBUTION OF CHANGES IN LSS SYMPTOM SEVERITY AND PHYSICAL FUNCTION SCALE SCORES FROM BASELINE AT 1, 2, AND 3 MONTHS OF FOLLOW-UP.

	Improvement from Baseline					
	LSS Symptom Severity Scale			LSS Physical Function Scale		
	Placebo	ESI		Placebo	ESI	
Time	Mean (SD)	Mean (SD)	p-value*	Mean (SD)	Mean (SD)	p-value*
1 Month	-0.06 (0.73)	-0.54 (0.80)	0.0076	-0.04 (0.77)	-0.57 (0.70)	0.0018
2 Months	-0.14 (0.58)	-0.42 (0.66)	0.0932	-0.19 (0.99)	-0.59 (0.67)	0.0824
3 Months	-0.06 (0.69)	-0.35 (0.73)	0.0731	-0.09 (0.99)	-0.27 (0.76)	0.3731

*Student t-test for difference between placebo and ESI groups
LSS: lumbar spinal stenosis
ESI: epidural steroid injection
SD: standard deviation

possibly random variation between results observed at different times. To address these concerns and to increase statistical power, the main analyses for the first three months rely on repeated measures analysis of variance with mixed models.

5.3.1.1 LSS symptom severity scale

Table 5-15 summarizes results of multivariable repeated measures modeling of the LSS symptom severity scale scores across the first three months of follow-up. Models 1-3 (Table 5-15) focus on the effects of treatment and time, while adjusting for baseline score only. Model 1 shows that the treatment has a statistically marginal significant effect (p=0.0508). Among patients with the same baseline score, those in the ESI group improved on average by 0.23 (95% CI: -0.45, 0.00) more than those in the placebo group. Model 2 shows that this result is not changed when the treatment effect is additionally adjusted for the effect of time since baseline. It also indicates that there was no systematic tendency for the mean score of all patients to change over time, as the effect of time is very close to 0 (0.05 increase in score with each additional month). Finally, Model 3 further supports that there is no systematic tendency for the treatment effect to change with time, as the time*treatment interaction is not statistically significant (p=0.3535), even if there is some trend for the treatment effect to decrease with time. As expected, in all models the baseline score is a very significant predictor of the scores at 1-3 months. Models 4-6 (Table 5-15) help investigate if the above results are robust with respect to adjustment for a number of *a priori* selected covariates. Model 4 shows that the time*treatment interaction remains statistically non-significant (p=0.3818) after adjusting for all the covariates. When this interaction is excluded (Table 5-15, Model 5), the adjusted treatment effect is almost exactly the same as the effect for Models 1 and 2 and remains statistically marginally significant (p=0.0575). Model 5 also indicates that most covariates did not have statistically significant association with the improvement in the LSS symptom severity scale score. The exception is physician's confidence in the LSS diagnosis, where for each 1 point increase on the 0-10 confidence scale the expected improvement increased by 0.13 (95% CI: -0.27, 0.02; p=0.0944). There was some trend for patients with secondary or higher education to show slightly greater improvement and

for those with a history of cardiovascular disease to have somewhat worse outcomes, but both associations did not reach statistical significance. Model 5 served as the basic model to test if the treatment effect depends on some covariates. When interactions between a particular covariate and treatment were added, one at a time to Model 5, most were statistically definitely non-significant (all p-values > 0.20). By contrast, a very significant interaction was found with high blood pressure (HBP) (p=0.0091), as shown in Model 6 (Table 5-15). Model 6 of Table 5-15 indicates that those without high blood pressure (HBP=0) experience a statistically significant treatment benefit (-0.50, 95% CI: -0.80, -0.20; p=0.0016), while those with the history of HBP treatment do not show any benefit of ESI (mean estimated change in this group is 0.17 higher, i.e. worse, than in the placebo group). Models 7-10 of Table 5-15 report results of analyses limited to those patients not currently being treated for high blood pressure. Model 10 shows that after adjusting for covariates, there was a definite statistically significant effect of treatment, with an average improvement of –0.46 over the placebo group for the three months (Table 5-15, Model 10: 95% CI: -0.81, -0.11; p=0.0113). The time*treatment interaction term was definitely non-significant in this sub-group (p=0.5224, Table 5-15, Model 9), indicating that the beneficial effect of treatment is quite stable in the first 3 months.

TABLE 5-15: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS SYMPTOM SEVERITY SCALE SCORE AS OUTCOME (N= 80)

	Model 1		Model 2		Model 3	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[(a)]	-0.23*	(-0.45, 0.00)	-0.22*	(-0.45, 0.00)	-0.31**	(-0.61, -0.02)
Baseline LSS symptom severity score	0.50***	(0.31, 0.69)	0.50***	(0.31, 0.69)	0.50***	(0.31, 0.69)
Time (months)			0.05	(-0.04, 0.15)	0.10	(-0.04, 0.23)
Time x Treatment Interaction					0.09	(-0.10, 0.27)

CI = confidence interval; LSS = lumbar spinal stenosis

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

* $0.05 \leq p < 0.10$
** $0.01 \leq p < 0.05$
*** $p < 0.01$

TABLE 5-15 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS SYMPTOM SEVERITY SCALE SCORE AS OUTCOME (N = 80)

	Model 4		Model 5		Model 6	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	-0.31**	(-0.61, -0.01)	-0.23*	(-0.46, 0.01)	-0.59***	(-0.86, -0.28)
Baseline LSS symptom severity score	0.47***	(0.27, 0.68)	0.47***	(0.27, 0.68)	0.43***	(0.23, 0.63)
Time (months)	0.10	(-0.04, 0.23)	0.06	(-0.04, 0.15)	0.05	(-0.04, 0.15)
Time x Treatment Interaction	0.08	(-0.10, 0.27)	-	-	-	-
Age (years)	-0.005	(-0.02, 0.01)	-0.005	(-0.02, 0.01)	-0.001	(-0.02, 0.01)
Male gender	-0.02	(-0.26, 0.22)	-0.02	(-0.26, 0.22)	-0.10	(-0.34, 0.13)
Duration of neurogenic claudication (months)	0.002	(-0.001, 0.01)	0.002	(-0.001, 0.01)	0.004*	(0.00, 0.01)
Secondary or Post Secondary education	-0.15	(-0.39, 0.09)	-0.15	(-0.39, 0.09)	-0.12	(-0.35, 0.11)
Physician confidence in LSS diagnosis (0-10)	-0.12*	(-0.27, 0.02)	-0.13*	(-0.27, 0.02)	-0.14**	(-0.29, -0.002)
Presence of cardiovascular disease history[b]	0.20	(-0.09, 0.49)	0.20	(-0.09, 0.49)	0.29**	(0.001, 0.57)
Presence of cardiovascular risk factors[c]	-0.05	(-0.33, 0.24)	-0.05	(-0.33, 0.24)	-0.08	(-0.35, 0.19)
Treated HBP	0.08	(-0.16, 0.32)	0.08	(-0.16, 0.33)	0.41**	(0.07, 0.76)
Treated HBP x Treatment Interaction	-	-	-	-	0.67***	(0.17, 1.17)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

* $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

TABLE 5-15 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS SYMPTOM SEVERITY SCALE SCORE AS OUTCOME IN THE SUB-GROUP OF PATIENTS WITHOUT HIGH BLOOD PRESSURE (N = 49)

	Model 7		Model 8		Model 9		Model 10	
	β	95% CI	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	-0.37**	(-0.68, -0.06)	-0.45**	(-0.84, -0.05)	-0.53**	(-0.96, -0.10)	-0.46**	(-0.81, -0.11)
Baseline LSS symptom severity score	0.38***	(0.14, 0.63)	0.38***	(0.14, 0.63)	0.34**	(0.09, 0.60)	0.34**	(0.09, 0.59)
Time (months)			0.14	(-0.05, 0.32)	0.14	(-0.05, 0.32)	0.09	(-0.03, 0.21)
Time x Treatment Interaction			0.08	(-0.16, 0.32)	0.08	(-0.17, 0.32)	-	-
Age (years)					0.002	(-0.02, 0.02)	-0.002	(-0.02, 0.02)
Male gender					-0.02	(-0.36, 0.32)	-0.02	(-0.36, 0.32)
Duration of neurogenic claudication (months)					0.001	(-0.005, 0.01)	0.001	(0.00, 0.01)
Secondary or Post Secondary education					-0.13	(-0.46, 0.21)	-0.13	(-0.46, 0.21)
Physician confidence in LSS diagnosis (0-10)					-0.13	(-0.31, 0.05)	-0.13	(-0.31, 0.05)
Presence of cardiovascular disease history[b]					0.36*	(0.00, 0.73)	0.36*	(0.00, 0.72)
Presence of cardiovascular risk factors[c]					0.02	(-0.38, 0.41)	0.02	(-0.37, 0.41)

CI = confidence interval; LSS = lumbar spinal stenosis;

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

* $0.05 \leq p < 0.10$ ** $0.01 \leq p < 0.05$ *** $p < 0.01$

5.3.1.2 LSS physical function scale

Table 5-16 shows the multivariable repeated measures analysis for LSS physical function scale scores across the first three months of follow-up. Model 1 presents the effect of treatment, adjusting only for baseline LSS physical function score. The treatment effect was found to be marginally non-significant (p=0.0725). In patients with similar baseline LSS physical function scores, the ESI group were shown to have a 0.25 greater improvement than placebo (95% CI: -0.52, 0.02). Model 2 shows that further adjustment for time elapsed since baseline did not change the treatment effect. The effect of time was found to be weak and statistically non-significant, displaying a 0.07 increase in mean score for each additional month. Model 3 indicates that the treatment effect displayed a trend to decrease over time, although the time*treatment interaction was not statistically significant (p=0.1102). Baseline LSS physical function scores were found to be definitely statistically significant predictors of scores from 1-3 months for all models. Models 4-6 in Table 5-16 display results adjusted for the remaining covariates, which do not seem to change the estimate of the treatment effect very much. Model 4 shows that the time*treatment interaction remains non-significant after adjusting for covariates (p=0.1166), and therefore, was removed from the final models. Model 5 shows that most covariates were not statistically significant predictors of physical function scores at 1-3 months, excepted for duration of neurgenic claudication (p=0.0496). An increase of 0.004 in score for every month of neurogenic claudication may seem small, however the mean duration of neurogenic claudication in the study was 33 months, translating into an estimated mean increase of 0.13 in score for the average LSS patient. Secondary or higher education was found to be a marginally significant predictor of physical function scores (p=0.0520). Those with secondary or higher education were found to have on average better physical function scores than those with lower education (-0.28, 95% CI: -0.56, 0.00).

Model 5 was the basis to test interactions between the treatment effect and individual covariates. As for the symptom severity scale, every interaction tested was found statistically non-significant ($p > 0.20$), except for a definitely significant interaction with history of treated high blood pressure (p=0.0032). Model 6 indicates that those

without HBP experience a statistically significant treatment benefit of 0.66 over placebo (95% CI: -1.02, -0.29; p=0.0006). By contrast, patients with HBP will experience no benefit from ESI, with the treated group averaging a 0.24 higher score than placebo (i.e. somewhat worse effect). The discovery of this significant treatment interaction with HBP lead to an investigation of a sub-group of patients without HBP (Table 5-16, Models 7-10). Models 7 shows a definite statistically significant treatment benefit, when adjusted only for baseline physical function score (-0.65, 95% CI, -0.98, -0.32; p=0.0002). Model 8 and 9 show results with the time*treatment interactions unadjusted and adjusted for covariates, and show that this interaction is definitely not significant in both models (p=0.3310 and p=0.3451, respectively). Model 10 shows the final model adjusted for all covariates in this sub-group. It indicates that among patients without HBP, a definite statistically significant improvement in physical function was seen on average in the ESI group over placebo for the first three months (-0.88, 95% CI: -1.23, -0.53; p=0.0001).

TABLE 5-16: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS PHYSICAL FUNCTION SCALE SCORE AS OUTCOME (N = 80)

	Model 1		Model 2		Model 3	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[(a)]	-0.25*	(-0.52, 0.02)	-0.25*	(-0.52, 0.02)	-0.42**	(-0.76, -0.08)
Baseline LSS physical function score	0.60***	(0.43, 0.77)	0.60***	(0.43, 0.77)	0.60***	(0.43, 0.77)
Time (months)			0.07	(-0.04, 0.17)	0.15**	(0.00, 0.30)
Time x Treatment Interaction					0.17	(-0.04, 0.37)

CI = confidence interval; LSS = lumbar spinal stenosis

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

* $0.05 \leq p < 0.10$
** $0.01 \leq p < 0.05$
*** $p < 0.01$

TABLE 5-16 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS PHYSICAL FUNCTION SCALE SCORE AS OUTCOME (N = 80)

	Model 4		Model 5		Model 6	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	-0.44**	(-0.78, -0.09)	-0.27*	(-0.55, 0.01)	-0.66***	(-1.02, -0.29)
Baseline LSS physical function score	0.59***	(0.40, 0.79)	0.59***	(0.40, 0.79)	0.63***	(0.44, 0.82)
Time (months)	0.15**	(0.00, 0.30)	0.07	(-0.04, 0.17)	0.07	(-0.03, 0.17)
Time x Treatment Interaction	0.16	(-0.04, 0.37)	-	-	-	-
Age (years)	0.005	(-0.01, 0.02)	0.005	(-0.01, 0.02)	0.01	(-0.01, 0.03)
Male gender	0.01	(-0.29, 0.31)	0.01	(-0.30, 0.31)	-0.07	(-0.36, 0.22)
Duration of neurogenic claudication (months)	0.004*	(0.00, 0.01)	0.004**	(0.00, 0.01)	0.006***	(0.00, 0.01)
Secondary or Post Secondary education	-0.28*	(-0.56, 0.00)	-0.28*	(-0.56, 0.00)	-0.22	(-0.49, 0.05)
Physician confidence in LSS diagnosis (0-10)	-0.07	(-0.24, 0.11)	-0.07	(-0.24, 0.11)	-0.10	(-0.27, 0.07)
Presence of cardiovascular disease history[b]	-0.004	(-0.35, 0.35)	-0.005	(-0.36, 0.35)	0.10	(-0.24, 0.44)
Presence of cardiovascular risk factors[c]	-0.05	(-0.39, 0.29)	-0.05	(-0.39, 0.29)	-0.09	(-0.41, 0.23)
Treated HBP	-0.13	(-0.43, 0.16)	-0.13	(-0.43, 0.16)	0.31	(-0.09, 0.71)
Treated HBP x Treatment Interaction	-	-	-	-	0.90***	(0.31, 1.48)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

* $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

TABLE 5-16 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS PHYSICAL FUNCTION SCALE SCORE AS OUTCOME IN THE SUB-GROUP OF PATIENTS WITHOUT HIGH BLOOD PRESSURE (N = 49)

	Model 7		Model 8		Model 9		Model 10	
	β	95% CI	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	-0.65***	(-0.98, -0.32)	-0.76***	(-1.16, 0.36)	-0.99***	(-1.41, -0.57)	-0.88***	(-1.23, -0.53)
Baseline LSS physical function score	0.91***	(0.70, 1.13)	0.91***	(0.70, 1.12)	0.99***	(0.76, 1.22)	0.99***	(0.76, 1.22)
Time (months)			0.13	(-0.04, 0.30)	0.13	(-0.04, 0.30)	0.07	(-0.04, 0.18)
Time x Treatment Interaction			0.11	(-0.12, 0.34)	0.11	(-0.12, 0.33)	-	-
Age (years)					0.01	(-0.01, 0.03)	0.01	(-0.01, 0.03)
Male Gender					-0.14	(-0.45, 0.18)	-0.14	(-0.45, 0.17)
Duration of neurogenic claudication (months)					0.009***	(0.003, 0.01)	0.009***	(0.003, 0.01)
Secondary or Post Secondary education					0.08	(-0.24, 0.40)	0.08	(-0.24, 0.40)
Physician confidence in LSS diagnosis (0-10)					-0.13	(-0.30, 0.04)	-0.13	(-0.30, 0.04)
Presence of cardiovascular disease history[b]					-0.05	(-0.41, 0.32)	-0.05	(-0.41, 0.32)
Presence of cardiovascular risk factors[c]					-0.12	(-0.49, 0.25)	-0.12	(-0.49, 0.25)

CI = confidence interval; LSS = lumbar spinal stenosis;

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

* $0.05 \leq p < 0.10$ ** $0.01 \leq p < 0.05$ *** $p < 0.01$

5.3.1.3 LSS satisfaction scale

The LSS satisfaction scale was administered at one, two and three months. The mean satisfaction scale score has a possible range between 1 (very satisfied) and 4 (very dissatisfied). Table 5-17 shows the mean LSS satisfaction scale scores for ESI and placebo groups. As expected, the treatment group consistently displayed higher satisfaction with ESI than placebo for 1, 2, and 3 months follow-up. Scores between ESI and placebo groups were found to be statistically significantly different at two months (2.19 vs. 2.77; p=0.0315), whereas the results at 3 months and especially at one month are more ambiguous. However, these unadjusted results should be interpreted with caution for reasons explained in Section 5.3.1. Thus, as for the other LSS scales, a repeated measures analysis of variance with mixed models was performed for results over the first three months.

Table 5-18 summarizes the multivariable repeated measures analysis for the LSS satisfaction scale over the first three months. Models 1-3 investigate effects of time and treatment adjusted for baseline LSS symptom severity and LSS physical function scale scores. Model 1 shows that for subjects with similar baseline symptom severity and physical function scores, the ESI group had on average 0.44 greater satisfaction over the first three months than placebo (95% CI: -0.81, -0.07; p=0.02). Additional adjustment for time elapsed since baseline did not change the treatment effect (Table 5-18, Model 2). The effect of time was close to zero (-0.02, 95%: -0.14, 0.11; p=0.7940), indicating no systematic change in score since baseline. The time*treatment interaction term was not statistically significant (p=0.6655). In all models, baseline symptom severity or physical function scores were unexpectedly not found to be statistically significant predictors of LSS satisfaction scores at 1-3 months. This may suggest that patients reported the level of their satisfaction based on changes in symptom severity and physical function, regardless of the baseline severity of their conditions. In Table 5-18, Models 4-6 focus on results with adjustments for all other covariates. Model 4 shows that the time*treatment interaction remains statistically non-significant (p=0.6692). In Model 5, the removal of this interaction term produced a somewhat lower treatment effect than

TABLE 5-17: MEAN LSS SATISFACTION SCALE SCORES AT 1, 2, AND 3 MONTHS OF FOLLOW-UP (N=80).

	Mean LSS Satisfaction Score[a]		
	Placebo	ESI	
Time	Mean (SD)	Mean (SD)	p-value*
1 Month	2.51 (0.85)	2.22 (1.01)	0.1898
2 Months	2.77 (0.95)	2.19 (1.00)	0.0315
3 Months	2.52 (0.93)	2.12 (0.91)	0.0778

(a) possible range of mean score is 1-4, corresponding to, respectively, 'very satisfied', 'moderately satisfied', 'moderately dissatisfied', and 'very dissatisfied'

*Student t-test for difference between scores for placebo and ESI groups

LSS: lumbar spinal stenosis
ESI: epidural steroid injection
SD: standard deviation

TABLE 5-18: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS SATISFACTION SCALE SCORE AS OUTCOME (N =80)

	Model 1		Model 2		Model 3	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	-0.44**	(-0.81, -0.07)	-0.44**	(-0.81, -0.07)	-0.39*	(-0.83, 0.05)
Baseline LSS symptom severity score	0.14	(-0.19, 0.48)	0.14	(-0.19, 0.48)	0.14	(-0.19, 0.48)
Baseline LSS physical function score	0.03	(-0.22, 0.27)	0.03	(-0.22, 0.27)	0.03	(-0.22, 0.27)
Time (months)			-0.02	(-0.14, 0.11)	-0.04	(-0.22, 0.13)
Time x Treatment Interaction					-0.05	(-0.30, 0.19)

CI = confidence interval; LSS = lumbar spinal stenosis

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.
(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke
(c) includes those at risk for diabetes or hypercholesterolemia

* $0.05 \leq p < 0.10$
** $0.01 \leq p < 0.05$
*** $p < 0.01$

TABLE 5-18 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS SATISFACTION SCALE SCORE AS OUTCOME (N = 80)

	Model 4		Model 5		Model 6	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	-0.33	(-0.79, 0.13)	-0.38*	(-0.78, 0.01)	-0.81***	(-1.32, -0.30)
Baseline LSS symptom severity score	0.18	(-0.18, 0.54)	0.18	(-0.19, 0.54)	0.09	(-0.26, 0.45)
Baseline LSS physical function score	0.09	(-0.20, 0.38)	0.09	(-0.19, 0.38)	0.16	(-0.13, 0.44)
Time (months)	-0.04	(-0.22, 0.13)	-0.02	(-0.14, 0.11)	-0.02	(-0.14, 0.11)
Time x Treatment Interaction	-0.05	(-0.30, 0.19)	-	-	-	-
Age (years)	-0.02	(-0.04, 0.01)	-0.02	(-0.04, 0.01)	-0.01	(-0.04, 0.01)
Male gender	0.13	(-0.28, 0.54)	0.13	(-0.28, 0.55)	0.03	(-0.37, 0.44)
Duration of neurogenic claudication (months)	0.001	(-0.01, 0.01)	0.001	(-0.01, 0.01)	0.003	(-0.003, 0.01)
Secondary or Post Secondary education	-0.02	(-0.42, 0.37)	-0.02	(-0.42, 0.37)	0.03	(-0.35, 0.42)
Physician confidence in LSS diagnosis (0-10)	0.005	(-0.24, 0.25)	0.005	(-0.24, 0.25)	-0.03	(-0.27, 0.20)
Presence of cardiovascular disease history[b]	0.16	(-0.33, 0.64)	0.16	(-0.33, 0.64)	0.27	(-0.21, 0.75)
Presence of cardiovascular risk factors[c]	0.11	(-0.36, 0.58)	0.11	(-0.36, 0.58)	0.07	(-0.39, 0.53)
Treated HBP	-0.18	(-0.59, 0.23)	-0.18	(-0.59, 0.23)	0.34	(-0.23, 0.91)
Treated HBP x Treatment Interaction	-	-	-	-	1.06**	(0.22, 1.90)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure; * $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

TABLE 5-18 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE LSS SATISFACTION SCALE SCORE AS OUTCOME FOR THE SUB-GROUP OF PATIENTS WITHOUT HIGH BLOOD PRESSURE (N = 49)

	Model 7		Model 8		Model 9		Model 10	
	β	95% CI	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[(a)]	-0.91***	(-1.35, -0.48)	-0.81***	(-1.35, -0.27)	-0.93***	(-1.54, -0.33)	-1.03***	(-1.54, -0.51)
Baseline LSS symptom severity score	-0.21	(-0.58, 0.15)	-0.21	(-0.58, 0.16)	-0.26	(-0.66, 0.14)	-0.26	(-0.66, 0.14)
Baseline LSS physical function score	0.45***	(0.15, 0.76)	0.45***	(0.14, 0.76)	0.57***	(0.20, 0.95)	0.57***	(0.20, 0.95)
Time (months)			-0.04	(-0.29, 0.20)	-0.04	(-0.29, 0.21)	-0.02	(-0.15, 0.18)
Time x Treatment Interaction			-0.11	(-0.22, 0.43)	-0.10	(-0.23, 0.43)	-	-
Age (years)					-0.01	(-0.04, 0.02)	-0.01	(-0.04, 0.02)
Male gender					0.01	(-0.45, 0.47)	0.01	(-0.44, 0.47)
Duration of neurogenic claudication (months)					0.005	(-0.003,0.01)	0.005	(-0.003,0.01)
Secondary or Post Secondary education					0.19	(-0.27, 0.65)	0.20	(-0.26, 0.66)
Physician confidence in LSS diagnosis (0-10)					0.01	(-0.24, 0.25)	0.01	(-0.24, 0.26)
Presence of cardiovascular disease history[a]					0.13	(-0.39, 0.66)	0.13	(-0.39, 0.66)
Presence of cardiovascular risk factors[b]					-0.10	(-0.66, 0.46)	-0.10	(-0.66, 0.46)

CI = confidence interval; LSS = lumbar spinal stenosis; * $0.05 \le p < 0.10$ ** $0.01 \le p < 0.05$ *** $p < 0.01$

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

seen in previous unadjusted Models 1-2 (-0.38, 95% CI: -0.78, 0.01), which was found to be marginally statistically significant (p=0.0557). None of the covariates were found to be statistically significantly associated with satisfaction scores. Model 5 was considered the final model, in which interactions of treatment with individual covariates were tested, one by one. None of these interactions were found to be statistically significant (all p-values > 0.20), except for HBP and treatment (p=0.0146). As for the other LSS scales, patients without HBP were found to experience a statistically significant treatment benefit (p=0.0022), with the ESI group on average displaying 0.81 greater improvement in satisfaction over the placebo group (95% CI: -1.32, -0.30). In contrast, those with HBP did not show any benefit from ESI (mean estimated change in ESI group is 0.25 higher, i.e. worse, than placebo group). Models 7-10 (Table 5-18) investigate the benefits of treatment in a sub-group of patients without HBP (n=49). Model 7 shows a statistically significant treatment benefit when adjusted for only baseline symptom severity and physical function scores (-0.91, 95% CI: -1.35, -0.48; p=0.0001). The time*treatment interaction was not found to be statistically significant (p=0.5082, Model 8), and remained non-significant when adjusted for the remaining covariates (p=0.5456, Model 9). This indicates the treatment effect is quite stable over the first three months. Thus, the final model without the time*treatment interaction, adjusted for covariates is shown as Model 10 in Table 5-18. There was a definite statistically significant treatment benefit in this sub-group, with an average improvement in satisfaction of 1.03 in the ESI group over placebo for the three months. The model also indicates that most covariates did not have statistically significant association with the improvement in the LSS satisfaction scale score. The exception was baseline LSS physical function score, where for each 1 point increase (worsening physical function), the expected improvement in satisfaction decreased by 0.57 (95% CI: 0.20, 0.95; p=0.0038). In contrast, higher baseline symptom severity score resulted in lower overall satisfaction scores (more satisfied), although this association did not reach statistical significance (-0.26, 95% CI: -0.66, 0.14; p=0.1870).

5.3.2 Results for the first three months of follow-up – Secondary outcome measures

Table 5-19 shows the improvements in scores from baseline for the following secondary outcomes: Quebec back pain disability scale and the physical and mental components of the SF-36 scale. No statistically significant differences in improvements were seen between ESI and placebo groups for either secondary outcome at 1, 2, or 3 months (Table 5-19). For reasons outlined before, these results should be interpreted with care. Thus, to increase precision and to adjust for baseline scale scores and for covariates, multivariable repeated measures analysis of variance for mixed models was performed for each of these secondary outcomes.

5.3.2.1 Quebec back pain disability scale

The Quebec back pain scale (QBPDS) is a 20-item questionnaire assessing difficulty in performance of certain activities because of the back. The scale was scored from 0-10, where 0 represented no difficulty to 10 representing unable to do the activity. Multivariable repeated measures analysis over 3 months for the QBPDS, adjusted for baseline score did not show a significant improvement between treatment and control groups (Table 5-20, Model 1: -0.17, 95% CI: -0.58, 0.23; p=0.4012). Adjustment for the effect of time did not change the results (Model 2, Table 5-20). In Model 3 of Table 5-20, the time*treatment interaction was found to be worthy of further investigation (p=0.1037). After adjusting for covariates, the model with the time*treatment interaction (p=0.1070) revealed a marginally significant treatment effect at one month (Table 5-20, Model 4: -0.52, 95% CI: -1.05, 0.01; p=0.0542), but this effect tended to decrease with increasing follow-up time. This improvement is reduced to 0.25 at two months and to no improvement at three months. As the interaction was marginally non-significant, Model 5 shows the overall model for the three months, adjusted for covariates, but without the time*treatment interaction term. There was a somewhat greater trend for improvement in the ESI group over placebo for this model than the effect seen in the unadjusted models 1-2. Despite this greater improvement, the treatment effect remained statistically

TABLE 5-19: DISTRIBUTION OF CHANGES IN QUEBEC BACK PAIN DISABILITY SCALE AND SF-36 SCALE SCORES FROM BASELINE AT 1, 2, AND 3 MONTHS OF FOLLOW-UP (N=80).

	Improvement from Baseline								
	Quebec Back Pain Disability Scale[a]			SF-36 Scale[b]					
				Physical Component (SF-36p)			Mental Component (SF-36m)		
	Placebo	ESI		Placebo	ESI		Placebo	ESI	
Time	Mean (SD)	Mean (SD)	p-value*	Mean (SD)	Mean (SD)	p-value*	Mean (SD)	Mean (SD)	p-value*
1 Month	-0.13 (1.19)	-0.55 (1.30)	0.1435	0.64 (6.66)	3.52 (8.10)	0.1157	0.93 (11.7)	0.07 (8.29)	0.7340
2 Months	-0.22 (1.31)	-0.66 (0.92)	0.1416	0.64 (8.28)	3.85 (7.57)	0.1550	2.41 (11.8)	-0.62 (9.44)	0.3161
3 Months	-0.23 (1.18)	-0.09 (1.11)	0.5832	2.20 (7.68)	2.28 (7.60)	0.9654	1.08 (9.84)	-1.68 (8.29)	0.2187

(a) The Quebec back pain disability scale was scored from 0-10, where 0 represented no difficulty to 10 representing unable to do the activity (improvement indicated by a negative change in score from baseline)
(b) The SF-36 scale was scored from 0-100, where 0 represented poor health to 100 representing excellent health

*Student t-test for difference between placebo and ESI groups
LSS: lumbar spinal stenosis
ESI: epidural steroid injection
SD: standard deviation
SF-36p: Physical Component Summary – SF-36 Scale
SF-36m: Mental Component Summary – SF-36 Scale

TABLE 5-20: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE QUEBEC BACK PAIN SCALE SCORE AS OUTCOME (N=80)

	Model 1		Model 2		Model 3	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[(a)]	-0.17	(-0.58, 0.23)	-0.17	(-0.58, 0.23)	-0.44*	(-0.95, 0.08)
Baseline Quebec back pain scale score	0.85***	(0.72, 0.98)	0.85***	(0.72, 0.98)	0.85***	(0.72, 0.98)
Time (months)			0.08	(-0.08, 0.24)	0.22*	(-0.02, 0.45)
Time x Treatment Interaction					0.27	(-0.05, 0.59)

CI = confidence interval; LSS = lumbar spinal stenosis

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.
(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke
(c) includes those at risk for diabetes or hypercholesterolemia

* $0.05 \leq p < 0.10$
** $0.01 \leq p < 0.05$
*** $p < 0.01$

TABLE 5-20 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE QUEBEC BACK PAIN SCALE SCORE AS OUTCOME (N=80)

	Model 4		Model 5		Model 6	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	-0.52*	(-1.05, 0.01)	-0.26	(-0.68, 0.16)	-0.89***	(-1.42, 0.35)
Baseline Quebec back pain scale score	0.78***	(0.64, 0.92)	0.78***	(0.64, 0.92)	0.77***	(0.64, 0.90)
Time (months)	0.21*	(-0.02, 0.45)	0.08	(-0.08, 0.24)	0.08	(-0.08, 0.23)
Time x Treatment Interaction	0.26	(-0.06, 0.58)	-	-	-	-
Age (years)	-0.001	(-0.03, 0.03)	-0.001	(-0.03, 0.03)	0.01	(-0.02, 0.03)
Male gender	-0.29	(-0.75, 0.17)	-0.29	(-0.75, 0.17)	-0.46**	(-0.91, -0.02)
Duration of neurogenic claudication (months)	0.006*	(0, 0.01)	0.006*	(0, 0.01)	0.008**	(0.002, 0.01)
Secondary or Post Secondary education	-0.48**	(-0.90, -0.05)	-0.48**	(-0.90, -0.05)	-0.39*	(-0.79, -0.02)
Physician confidence in LSS diagnosis (0-10)	-0.13	(-0.40, 0.13)	-0.13	(-0.40, 0.13)	-0.18	(-0.43, 0.07)
Presence of cardiovascular disease history[b]	0.15	(-0.37, 0.67)	0.15	(-0.37, 0.67)	0.35	(-0.16, 0.85)
Presence of cardiovascular risk factors[c]	-0.05	(-0.56, 0.46)	-0.05	(-0.56, 0.47)	-0.11	(-0.59, 0.37)
Treated HBP	0.04	(-0.40, 0.48)	0.04	(-0.40, 0.49)	0.78**	(0.18, 1.37)
Treated HBP x Treatment Interaction	-	-	-	-	1.48***	(0.63, 2.34)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure * $0.05 \le p < 0.10$; ** $0.01 \le p < 0.05$; *** $p < 0.01$

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

TABLE 5-20 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE QUEBEC BACK PAIN SCALE SCORE AS OUTCOME FOR THE SUB-GROUP OF PATIENTS WITHOUT HIGH BLOOD PRESSURE (N = 49)

	Model 7		Model 8		Model 9		Model 10	
	β	95% CI	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo[(a)]	-0.57**	(-1.12, -0.02)	-0.82**	(-1.50, -0.14)	-1.12***	(-1.85, -0.39)	-0.88***	(-1.49, -0.27)
Baseline Quebec back pain scale score	0.90***	(0.73, 1.07)	0.90***	(0.73, 1.07)	0.80***	(0.62, 0.99)	0.80***	(0.62, 0.99)
Time (months)			0.22	(-0.09, 0.52)	0.21	(-0.09, 0.51)	0.07	(-0.12, 0.26)
Time x Treatment Interaction			0.25	(-0.64, 0.15)	0.24	(-0.15, 0.63)	-	-
Age (years)					0.003	(-0.03, 0.04)	0.003	(-0.03, 0.04)
Male gender					-0.39	(-1, 0.21)	-0.40	(-1.00, 0.21)
Duration of neurogenic claudication (months)					0.01*	(-0.001, 0.02)	0.009*	(-0.006,0.02)
Secondary or Post Secondary education					-0.51*	(-1.09, 0.07)	-0.51*	(-1.09, 0.07)
Physician confidence in LSS diagnosis (0-10)					-0.14	(-0.46, 0.18)	-0.14	(-0.46, 0.18)
Presence of cardiovascular disease history[(b)]					0.32	(-0.33, 0.98)	0.33	(-0.33, 0.98)
Presence of cardiovascular risk factors[(c)]					-0.14	(-0.83, 0.55)	-0.13	(-0.82, 0.56)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure * $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

non-significant over the three months (-0.26, 95% CI: -0.68, 0.16; p=0.2263). Most covariates were not found to be statistically significant predictors of QBPDS scores for the three months except secondary education and baseline QBPDS score. As expected, baseline QBPDS score was a significant predictor of a higher QBPDS score for three months (p=0.0001). Patients with secondary or higher education had statistically significant better QBPDS scores (-0.48, 95% CI: -0.90, -0.05; p=0.0299). Those patients who had longer duration of neurogenic claudication were found to have higher QBPDS scores (worse back pain), although this predictor was not found to be statistically significant (p=0.0940). Interactions of treatment with other covariates were tested by adding them individually to Model 5. Interactions with treatment proved not to be important (all p-values > 0.20) except high blood pressure (Model 6, p=0.0009). As for all the primary outcome measures, those not being treated for HBP displayed a statistically significant treatment benefit compared to placebo (Table 5-20, Model 6: -0.89, 95% CI: -1.42, -0.35; p=0.0015). Model 6 also showed that male subjects on average have significantly better outcomes compared to female subjects (-0.46, 95% CI: -0.91, -0.02; p=0.0409). It also showed that patients with HBP do not experience any treatment benefit over placebo. In fact, the mean estimated change in the ESI group was 0.59 higher (i.e. worse, than in the placebo group), although this effect was not statistically significant. The significant HBP*treatment interaction lead to further investigation of a sub-group of patients without high blood pressure (Table 5-20, Models 7-10). Model 7 shows that within this sub-group, there was a statistically significant treatment benefit in the ESI group over the placebo group, adjusting only for baseline score (-0.57, 95% CI: -1.12, -0.02; p=0.0440). The time*treatment interaction was statistically non-significant (Model 8, p=0.2171), and remained non-significant after adjusting for covariates (Model 9, p=0.2208). After the interaction of treatment and time was dropped, the final model (adjusted for remaining covariates) showed a 0.88 greater improvement in QBPDS score in the ESI group over placebo group (95% CI: -1.49, -0.27; p=0.0061).

5.3.2.2 Medical Outcomes Study (MOS) Short Form 36 item questionnaire (SF-36)

The physical and mental health components of the SF-36 (abbreviated SF-36p and SF-36m, respectively) were separately used as secondary outcomes in the study (possible score range for each scale, 0-100). Higher scores reflect fewer physical limitations and disabilities in the SF-36p, while higher SF-36m scores indicate fewer emotional and psychological problems. Table 5-19 shows differences in scores from baseline for both the SF-36p and SF-36m scales individually at 1, 2, and 3 months. Positive differences for the SF-36p and SF-36m indicate improvement. No significant differences were found between ESI and placebo groups at either 1, 2, or 3 months, but for reasons outlined previously these results were interpreted with caution.

Multivariable repeated measures analysis showed no significant improvement on either the SF-36p or SF-36m, between treatment and placebo groups over the three months (Table 5-21 and 5-22, Model 1 in both tables). These models were adjusted for the respective baseline scaled score only. Further adjustments for the effect of time did not change the results. Time*treatment interactions were tested in both the SF-36p and the SF-36m, but found to be non-significant in both the adjusted and unadjusted models. Model 5 shows the final model (without time*treatment interaction term) for both SF-36p and SF-36m scales in Tables 5-21 and 5-22. This model shows that after adjusting for covariates, the treatment effect remained non-significant over three months. Interactions of covariates with treatment were tested by adding them individually to Model 5 in Table 5-21 and 5-22, but were not found to be statistically significant in either scale (p-values > 0.20).

TABLE 5-21: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE PHYSICAL COMPONENT OF THE SF-36 SCALE SCORE AS OUTCOME (N=80)

	Model 1		Model 2		Model 3	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo	1.46	(-1.38, 4.31)	1.46	(-1.39, 4.31)	2.88	(-0.67, 6.42)
Baseline Physical component SF-36 score	0.77***	(0.60, 0.94)	0.77***	(0.60, 0.94)	0.77***	(0.60, 0.94)
Time (months)			0.12	(-0.92, 1.16)	-0.63	(-2.15, 0.89)
Time x Treatment Interaction					-1.41	(-3.49, 0.68)

CI = confidence interval; LSS = lumbar spinal stenosis

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

* $0.05 \leq p < 0.10$

** $0.01 \leq p < 0.05$

*** $p < 0.01$

TABLE 5-21 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE PHYSICAL COMPONENT OF THE SF-36 SCALE SCORE AS OUTCOME (N=80)

	Model 4		Model 5	
	β	95% CI	β	95% CI
Treatment vs. Placebo	2.63	(-0.95, 6.21)	1.25	(-1.66, 4.16)
Baseline Physical component SF-36 score	0.74***	(0.56, 0.93)	0.74***	(0.56, 0.93)
Time (months)	-0.61	(-2.12, 0.90)	0.13	(-0.91, 1.16)
Time x Treatment Interaction	-1.38	(-3.45, 0.69)	-	-
Age (years)	0.16*	(-0.01, 0.34)	0.16*	(-0.01, 0.34)
Male Gender	2.41	(-0.67, 5.49)	2.41	(-0.68, 5.49)
Duration of neurogenic claudication (months)	-0.04	(-0.08, 0.01)	-0.04	(-0.08, 0.01)
Secondary or Post Secondary education	1.16	(-1.87, 4.19)	1.19	(-1.84, 4.22)
Physician confidence in LSS diagnosis (0-10)	0.97	(-0.92, 2.87)	0.95	(-0.95, 2.85)
Presence of cardiovascular disease history[b]	-2.73	(-6.21, 0.74)	-2.75	(-6.23, 0.73)
Presence of cardiovascular risk factors[c]	-2.54	(-6.08, 1.01)	-2.55	(-6.11, 1.00)
Treated HBP	0.02	(-3.05, 3.09)	0.02	(-3.05, 3.10)

CI = confidence interval; LSS = lumbar spinal stenosis * $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

TABLE 5-22: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE MENTAL COMPONENT OF THE SF-36 SCALE SCORE AS OUTCOME (N=80)

	Model 1		Model 2		Model 3	
	β	95% CI	β	95% CI	β	95% CI
Treatment vs. Placebo	0.06	(-3.47, 3.35)	0.05	(-3.46, 3.36)	-0.99	(-3.30, 5.27)
Baseline Mental component SF-36 score	0.59***	(0.43, 0.74)	0.59***	(0.43, 0.74)	0.58***	(0.43, 0.74)
Time (months)			-0.37	(-1.64, 0.91)	-0.92	(-2.78, 0.95)
Time x Treatment Interaction					-1.03	(-1.52, 3.58)

CI = confidence interval; LSS = lumbar spinal stenosis

(a) Estimated difference between mean change from baseline in the treatment vs. placebo groups, adjusted for other covariates in the specific model. Negative sign indicates greater improvement (decrease in scores) in the treatment group.

* $0.05 \leq p < 0.10$

** $0.01 \leq p < 0.05$

*** $p < 0.01$

TABLE 5-22 CONTINUED: MULTIVARIABLE REPEATED MEASURES ANALYSIS OVER 3 MONTHS FOR THE MENTAL COMPONENT OF THE SF-36 SCALE SCORE AS OUTCOME.

	Model 4		Model 5	
	β	95% CI	β	95% CI
Treatment vs. Placebo[a]	0.78	(-3.81, 5.37)	-0.28	(-4.06, 3.50)
Baseline Mental component SF-36 score	0.60***	(0.43, 0.76)	0.60***	(0.43, 0.76)
Time (months)	-0.92	(-2.80, 0.96)	-0.35	(-1.63, 0.93)
Time x Treatment Interaction	-1.06	(-3.64, 1.51)	-	-
Age (years)	-0.10	(-0.33, 0.12)	-0.10	(-0.33, 0.12)
Male gender	-1.31	(-4.97, 2.34)	-1.31	(-4.97, 2.34)
Duration of neurogenic claudication (months)	-0.02	(-0.07, 0.04)	-0.02	(-0.07, 0.04)
Secondary or Post Secondary education	-2.11	(-5.96, 1.74)	-2.08	(-5.93, 1.77)
Physician confidence in LSS diagnosis (0-10)	1.22	(-1.22, 3.65)	1.20	(-1.23, 3.63)
Presence of cardiovascular disease history[b]	1.30	(-3.13, 5.74)	1.29	(-3.14, 5.72)
Presence of cardiovascular risk factors[c]	-0.35	(-4.86, 4.16)	-0.37	(-4.87, 4.14)
Treated HBP	-0.92	(-4.77, 2.93)	-0.92	(-4.77, 2.93)

CI = confidence interval; LSS = lumbar spinal stenosis * $0.05 \le p < 0.10$; ** $0.01 \le p < 0.05$; *** $p < 0.01$

(b) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

(c) includes those at risk for diabetes or hypercholesterolemia

5.3.3 Six month results

Analyses of outcomes at six months were performed on the 45 patients for whom the randomization code was not broken. Twenty-two of these patients remained randomized to the control group and 23 patients were still randomized to the treatment group. The focus of the analyses was to assess if the potential treatment benefit persists until 6 months since the first injection. Initial unadjusted comparisons of mean changes between baseline and 6 months for LSS symptom severity and physical function scales are shown in Table 5-23. No difference was seen between ESI and placebo groups. Unadjusted mean comparisons of satisfaction scale scores for ESI and placebo groups were also not found to be significantly different at 6 months (Table 5-24). The following results report the multiple linear regression models at six months with adjustments for various covariates.

Because each patient contributed only one observation and because of the reduced sample size, it was not possible to adjust for all variables included in the analyses of the first 3 months. In accordance with the requirement of at least 5 observations per each variable in the model, only those covariates that were shown to have p-values < 0.30 in the three month repeated measures analysis were kept in the six month models. It was assumed that those covariates not found to be statistically significant at three months were unlikely to have an effect at six months. This produced regression models with less than 8 variables, which meets the requirement given a sample size of 45.

Table 5-25 shows the results of multiple linear regression for the LSS symptom severity scale as outcome at 6 months. There was no statistically significant treatment effect on symptom severity, with adjustment for only baseline LSS symptom severity score (Table 5-25, Model 1: 0.12, 95% CI: -0.33, 0.57; p=0.6054). Covariates such as age, sex, secondary or higher education, and presence of cardiovascular risk factors were not shown to be statistically significant predictors ($p \geq 0.30$) at the three month repeated measures analysis and thus excluded to maximize power because of the reduced sample size of 45 at six months. After adjusting for the remaining covariates (i.e. duration of neurogenic claudication, physician confidence, presence of cardiovascular disease history, and treated HBP), the overall model remained non-significant (p=0.3976), and

TABLE 5-23: DISTRIBUTION OF CHANGES IN LSS SYMPTOM SEVERITY AND PHYSICAL FUNCTION SCALE SCORES FROM BASELINE AT 6 AND 12 MONTHS OF FOLLOW-UP (N=45 AND N=29, RESPECTIVELY).

	Improvement from Baseline					
	LSS Symptom Severity Scale			LSS Physical Function Scale		
	Placebo	ESI		Placebo	ESI	
Time	Mean (SD)	Mean (SD)	p-value*	Mean (SD)	Mean (SD)	p-value*
6 Months	-0.27 (0.90)	-0.41 (0.72)	0.5738	-0.09 (1.07)	-0.32 (1.03)	0.4621
12 Months	-0.28 (0.30)	-0.61 (0.70)	0.1091	-0.34 (0.70)	-0.50 (0.91)	0.6173

*Student t-test for difference between placebo and ESI groups
LSS: lumbar spinal stenosis
ESI: epidural steroid injection
SD: standard deviation

TABLE 5-24: MEAN LSS SATISFACTION SCALE SCORES AT 6 AND 12 MONTHS OF FOLLOW-UP (N=45 AND N=29, RESPECTIVELY).

	Mean LSS Satisfaction Score[a]		
	Placebo	ESI	
	Mean (SD)	Mean (SD)	p-value*
Time			
6 Months	2.13 (1.08)	1.91 (0.94)	0.4673
12 Months	1.74 (0.60)	1.53 (0.90)	0.4641

(a) possible range of mean score is 1-4, corresponding to, respectively, 'very satisfied', 'moderately satisfied', 'moderately dissatisfied', and 'very dissatisfied'

*Student t-test for difference between scores for placebo and ESI groups

LSS: lumbar spinal stenosis
ESI: epidural steroid injection
SD: standard deviation

TABLE 5-25: MULTIPLE LINEAR REGRESSION AT 6 MONTHS FOR THE LSS SYMPTOM SEVERITY SCALE SCORE AS OUTCOME (N=45)

	Model 1		Model 2		Model 3	
$R^{2\,(a)}$	0.0949		0.1445		0.2051	
p-value (overall F-test)[(b)]	0.1232		0.3976		0.2496	
	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI
Treatment vs. Placebo	0.12	(-0.33, 0.57)	0.04	(-0.45, 0.53)	-0.33	(-0.98, 0.32)
Baseline LSS symptom severity score	0.35*	(-0.04, 0.74)	0.31	(-0.10, 0.72)	0.29	(-0.12, 0.70)
Duration of neurogenic claudication (months)			0.007	(-0.003, 0.02)	0.008*	(0.00, 0.02)
Physician confidence in LSS diagnosis (0-10)			0.001	(-0.30, 0.31)	0.02	(-0.27, -0.31)
Presence of cardiovascular disease history[(d)]			-0.01	(-0.60, 0.58)	0.08	(-0.51, 0.67)
Treated HBP			0.08	(-0.41, 0.57)	-0.32	(-0.99, 0.35)
Treated HBP x Treatment Interaction			-	-	0.78	(-0.12, 1.68)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(a) R^2 = property of the total variance in the outcome explained by all variables in the model

(b) F-test (with number of degrees-of-freedom equal to the number of independent variables in the model) for testing H_0 that none of the independent variables has an association with the outcome

(c) β = regression coefficient corresponding to the estimated effect of changing a quantitative variable 1 unit, or to the mean difference between the two categories of a binary variable, adjusted for all other variables in the model

(d) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

* $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

the treatment effect also remained statistically non-significant and very close to zero (Table 5-25, Model 2: 0.04, 95% CI: -0.45, 0.53; p=0.8772). A treatment*HBP interaction was not found to be significant (p=0.1016), but seemed to indicate a greater treatment effect for those without HBP (Table 5-25, Model 3: -0.33, 95% CI: -0.98, 0.32; p=0.3234).

Using the LSS physical function scale as outcome at six months showed similar non-significant findings. Unadjusted changes in LSS physical function score from baseline were not shown to be significantly different between ESI and placebo groups (Table 5-23). Table 5-26 shows the multiple linear regression models for LSS physical function score as outcome. There was no treatment effect in the unadjusted model (only controlled for baseline physical function score, not covariates) (Model 1: -0.04, 95% CI: -0.63, 0.55; p=0.8862), which remained non-significant after adjusting for duration of neurogenic claudication, secondary education, physician confidence, and treated HBP (Model 2: -0.20, 95% CI: -0.85, 0.45; p=0.5413). Covariates such as age, sex, presence of cardiovascular disease, or presence of cardiovascular risk factors were not shown to be statistically significant at three months and thus excluded from the six month analysis ($p \geq 0.30$). Treatment interaction with HBP was not found to be statistically significant at six months (Table 5-26, Model 3: p=0.4765). Despite the non-significant interaction, those without HBP displayed a trend for greater improvement in physical function for those in the treatment versus control group (Table 5-26, Model 3: -0.43, 95% CI: -1.31, 0.45; p=0.3535).

Table 5-24 shows that the unadjusted differences in satisfaction scores among ESI and placebo were not significantly different. Table 5-27 displays results of the multiple linear regression at six months with the LSS satisfaction scale score as outcome (score range, 1-4). Model 1 showed a non-significant treatment effect when adjusted for baseline LSS symptom severity and physical function scores (-0.29, 95% CI: -0.92, 0.34; p=0.3832). Overall, Model 1 explained only 4.7% of the total variance in the LSS satisfaction score. Adjustment for the six months analysis was conducted for those covariates that displayed a p-value < 0.30 at the three month analysis (i.e. presence of cardiovascular disease and high blood pressure), while those that displayed p-values ≥ 0.30 at three months (i.e. age, sex, secondary education, physician confidence, duration

TABLE 5-26: MULTIPLE LINEAR REGRESSION AT 6 MONTHS FOR THE LSS PHYSICAL FUNCTION SCALE SCORE AS OUTCOME (N=45)

	Model 1		Model 2		Model 3	
$R^{2\,(a)}$	0.0893		0.1721		0.1835	
p-value (overall F-test)[(b)]	0.1401		0.2737		0.3336	
	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI
Treatment vs. Placebo	-0.04	(-0.63, 0.55)	-0.20	(-0.85, 0.45)	-0.43	(-1.31, 0.45)
Baseline LSS physical function score	0.40*	(0.008, 0.79)	0.35	(-0.06, 0.76)	0.38*	(-0.05, 0.81)
Duration of neurogenic claudication (months)			0.002	(-0.01, 0.01)	0.004	(-0.01, 0.02)
Secondary or Post Secondary education			-0.33	(-0.96, 0.30)	-0.32	(-0.95, 0.31)
Physician confidence in LSS diagnosis (0-10)			0.01	(-0.40, 0.42)	0.01	(-0.40, -0.42)
Treated HBP			0.46	(-0.17, 1.09)	0.22	(-0.68, 1.12)
Treated HBP x Treatment Interaction			-	-	0.44	(-0.78, 1.66)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(a) R^2 = property of the total variance in the outcome explained by all variables in the model

(b) F-test (with number of degrees-of-freedom equal to the number of independent variables in the model) for testing H_0 that none of the independent variables has an association with the outcome

(c) β = regression coefficient corresponding to the estimated effect of changing a quantitative variable 1 unit, or to the mean difference between the two categories of a binary variable, adjusted for all other variables in the model

* $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

TABLE 5-27: MULTIPLE LINEAR REGRESSION AT 6 MONTHS FOR THE LSS SATISFACTION SCALE SCORE AS OUTCOME (N=45)

	Model 1		Model 2		Model 3	
$R^{2\,(a)}$	0.0471		0.0523		0.0932	
p-value (overall F-test)[(b)]	0.5720		0.8243		0.6892	
	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI
Treatment vs. Placebo	-0.29	(-0.92, 0.34)	-0.27	(-0.93, 0.40)	-0.67	(-1.55, 0.21)
Baseline LSS symptom severity score	0.20	(-0.23, 0.63)	-0.19	(-0.64, 0.26)	-0.14	(-0.59, 0.31)
Baseline LSS physical function score	0.32	(-0.25, 0.89)	0.34	(-0.25, 0.93)	0.31	(-0.28, 0.90)
Presence of cardiovascular disease history[(d)]			0.13	(-0.67, 0.93)	0.24	(-0.58, 1.06)
Treated HBP			-0.10	(-0.73, 0.53)	-0.55	(-1.47, 0.37)
Treated HBP x Treatment Interaction			-	-	0.85	(-0.42, 2.12)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(a) R^2 = property of the total variance in the outcome explained by all variables in the model

(b) F-test (with number of degrees-of-freedom equal to the number of independent variables in the model) for testing H_0 that none of the independent variables has an association with the outcome

(c) β = regression coefficient corresponding to the estimated effect of changing a quantitative variable 1 unit, or to the mean difference between the two categories of a binary variable, adjusted for all other variables in the model

(d) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

* $0.05 \le p < 0.10$; ** $0.01 \le p < 0.05$; *** $p < 0.01$

of neurogenic claudication, and presence of cardiovascular risk factors) were excluded in order to limit number of covariates at six months, considering the smaller sample size of 45. Thus, adjusting for the selected covariates we found that those on treatment experienced better, but not statistically significant different satisfaction scores than the placebo group (Table 5-27, Model 2: -0.27, 95% CI: -0.93, 0.40; p=0.4199). Consistently with the two other scales, a treatment*HBP interaction was not statistically significant (Table 5-27, Model 3: p=0.1987). Although not statistically significant, patients not on medication for HBP were found to display a greater treatment effect (more satisfied) than those currently taking medication for HBP (Table 5-27, Model 3: -0.67, 95% CI: -1.55, 0.21; p=0.1452).

5.3.4 Twelve month results

At 12 months, 29 patients remained randomized in the study. Fourteen patients were in the control group, while 15 patients were in the treatment group. In the preliminary unadjusted analyses shown in Tables 5-23 and 5-24, no significant differences in improvements were found between ESI and placebo groups for the three scales. Analysis of the multiple linear regression also revealed no statistically significant improvement due to treatment at 12 months, in any of the three primary outcomes (i.e. LSS symptom severity scale, LSS physical function scale, LSS satisfaction scale). With 29 patients in the sample, a maximum of 5-6 variables was permitted in the regression models. Thus, similar to the 6-month analysis, covariates found to have $p \geq 0.30$ at the 3-month analysis were excluded in the 12-month analysis. Models with LSS symptom severity as outcome required excluding additional covariates such as duration of neurogenic claudication and physician confidence, to respect the critical value of at least 5 observations per regression parameter. The variable assessing physician confidence was also excluded from the models with LSS physical function score as outcome for similar reasons. The remaining part of this section explains in more detail, the non-significant findings found in the multiple linear regression analysis at 12 months.

Model 1 of Table 5-28 shows a non-significant treatment effect at 12 months for LSS symptom severity as outcome, unadjusted for covariates (-0.19, 95% CI: -0.33, 0.57; p=0.3486). Adjusting for presence of cardiovascular disease history and treated HBP produced a similar non-significant treatment effect (Table 5-28, Model 2: -0.18, 95% CI: -0.57, 0.21; p=0.3781). An interaction of treated HBP and treatment was tested, was completely non-significant (Table 5-28, Model 3: p=0.9323).

Testing of the LSS physical function scale score as outcome in a model not adjusted for covariates revealed no treatment effect from ESI (Table 5-29, Model 1: 0.00, 95% CI: -0.59, 0.59; p=0.9999), and adjusting for covariates produced similar non-significant improvement from treatment (Table 5-29, Model 2: -0.18, 95% CI: -0.71, 0.35; p=0.5018). It was interesting to note that secondary or higher educated patients reported significantly better physical function scores than patients with lower education (Table 5-29, Model 2: -0.73, 96%CI: -1.20, -0.26; p=0.0055). Patients being treated for HBP were also found to have significantly worse physical functional status than those not suffering from HBP (Table 5-29, Model 2: 0.60, 95% CI: 0.11, 1.09; p=0.0232). Model 3 in Table 5-29 shows that a HBP*treatment interaction was statistically completely non-significant (0.01, 95% CI: -1.01, 1.03; 0.9846).

Analysis of the LSS satisfaction scale score as outcome at 12 months revealed no significant score improvement from treatment, when adjusted for baseline LSS symptom severity and physical function scores (Table 5-30, Model 1: -0.30, 95% CI: -0.93, 0.33; p=0.3615). After adjustment for covariates, there was a trend for greater improvement in satisfaction scores among those treated with ESI versus the placebo group, but it did not reach statistical significance (Table 5-30, Model 2: -0.54, 95% CI: -1.13, 0.05; p=0.0828). A treatment*HBP interaction was not found to be statistically significant (Table 5-30, Model 3: 0.65, 95% CI: -0.59, 1.87; p=0.3181).

TABLE 5-28: MULTIPLE LINEAR REGRESSION AT 12 MONTHS FOR LSS SYMPTOM SEVERITY SCALE SCORE AS OUTCOME (N=29)

	Model 1		Model 2		Model 3	
$R^{2\,(a)}$	0.3835		0.4472		0.4850	
p-value (overall F-test)[(b)]	0.0019		0.0052		0.0063	
	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI
Treatment vs. Placebo	-0.19	(-0.33, 0.57)	-0.18	(-0.57, 0.21)	0.02	(-0.47, 0.51)
Baseline LSS symptom severity score	0.64***	(-0.04, 0.74)	0.64***	(0.33, 0.95)	0.66***	(0.35, 0.97)
Presence of cardiovascular disease history[(d)]			-0.46	(-0.99, 0.07)	-0.57*	(-1.12, -0.02)
Treated HBP			-0.05	(-0.44, 0.34)	0.24	(-0.35, 0.83)
Treated HBP x Treatment Interaction			-	-	-0.54	(-1.34, 0.26)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(a) R^2 = property of the total variance in the outcome explained by all variables in the model

(b) F-test (with number of degrees-of-freedom equal to the number of independent variables in the model) for testing H_0 that none of the independent variables has an association with the outcome

(c) β = regression coefficient corresponding to the estimated effect of changing a quantitative variable 1 unit, or to the mean difference between the two categories of a binary variable, adjusted for all other variables in the model

(d) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

* $0.05 \le p < 0.10$; ** $0.01 \le p < 0.05$; *** $p < 0.01$

TABLE 5-29: MULTIPLE LINEAR REGRESSION AT 12 MONTHS FOR LSS PHYSICAL FUNCTION SCALE SCORE AS OUTCOME (N=29)

	Model 1		Model 2		Model 3	
$R^{2\,(a)}$	0.2584		0.5869		0.5869	
p-value (overall F-test)[(b)]	0.0205		0.0006		0.0018	
	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI
Treatment vs. Placebo	0.00	(-0.59, 0.59)	-0.18	(-0.71, 0.35)	-0.19	(-0.92, 0.54)
Baseline LSS physical function score	0.60***	(0.20, 1.00)	0.51***	(0.16, 0.86)	0.51**	(0.14, 0.88)
Duration of neurogenic claudication (months)			-0.003	(-0.01, 0.005)	-0.003	(-0.01, 0.007)
Secondary or Post Secondary education			-0.73***	(-1.20, -0.26)	-0.73***	(-1.20, -0.26)
Treated HBP			0.60**	(0.11, 1.09)	0.60	(-0.14, 1.34)
Treated HBP x Treatment Interaction			-	-	0.01	(-1.01, 1.03)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(a) R^2 = property of the total variance in the outcome explained by all variables in the model

(b) F-test (with number of degrees-of-freedom equal to the number of independent variables in the model) for testing H_0 that none of the independent variables has an association with the outcome

(c) β = regression coefficient corresponding to the estimated effect of changing a quantitative variable 1 unit, or to the mean difference between the two categories of a binary variable, adjusted for all other variables in the model

* $0.05 \leq p < 0.10$; ** $0.01 \leq p < 0.05$; *** $p < 0.01$

TABLE 5-30: MULTIPLE LINEAR REGRESSION AT 12 MONTHS FOR LSS SATISFACTION SCALE SCORE AS OUTCOME (N=29)

	Model 1		Model 2		Model 3	
$R^{2\,(a)}$	0.0453		0.3026		0.3357	
p-value (overall F-test)[(b)]	0.7689		0.1336		0.1545	
	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI	$\beta^{(c)}$	95% CI
Treatment vs. Placebo	-0.30	(-0.93, 0.33)	-0.54*	(-1.13, 0.05)	-0.77*	(-1.50, 0.04)
Baseline LSS symptom severity score	0.03	(-0.42, 0.48)	-0.15	(-0.60, 0.30)	-0.07	(-0.54, 0.40)
Baseline LSS physical function score	0.18	(-0.33, 0.69)	0.18	(-0.27, 0.63)	0.14	(-0.33, 0.61)
Presence of cardiovascular disease history[(d)]			0.40	(-0.60, 1.40)	0.41	(-0.59, 1.41)
Treated HBP			-0.92**	(-1.56, -0.28)	0.50	(-0.52, -1.52)
Treated HBP x Treatment Interaction			-	-	0.65	(-0.59, 1.87)

CI = confidence interval; LSS = lumbar spinal stenosis; HBP = high blood pressure

(a) R^2 = property of the total variance in the outcome explained by all variables in the model

(b) F-test (with number of degrees-of-freedom equal to the number of independent variables in the model) for testing H_0 that none of the independent variables has an association with the outcome

(c) β = regression coefficient corresponding to the estimated effect of changing a quantitative variable 1 unit, or to the mean difference between the two categories of a binary variable, adjusted for all other variables in the model

(d) includes those with current symptoms of angina, or past history of cardiac surgery, myocardial infarction, or stroke

* $0.05 \le p < 0.10$; ** $0.01 \le p < 0.05$; *** $p < 0.01$

CHAPTER 6: DISCUSSION

To date, measures assessing quality of life and health status in LSS patients undergoing ESI therapy have been general in nature and have not directly addressed improvement. No specific measures exist which evaluate improvement in LSS patients from conservative therapy such as ESI. Improvement in symptom severity, functional capacity, and satisfaction from ESI treatment are direct measures that would be most relevant to LSS patients undergoing ESI therapy. These improvements also provide an objective method for clinicians to compare their clinical evaluations of individual patients.

In this thesis, I have investigated the efficacy of epidural steroid injection therapy as a treatment option for LSS patients through the analysis of a randomized control study. In order to ensure the meaningful interpretation of the results of this trial, it was also necessary to assess psychometric properties of the French-translated main outcome measures. The objective of the first part of the thesis was to measure the reliability, validity, and responsiveness of spinal stenosis scale instruments specific to the measurement of symptom severity, physical function, and satisfaction with conservative treatments such as ESI. My thesis shows that the modified symptom severity, physical function, and satisfaction scales are reliable, internally consistent, valid and sensitive to change in a French-Canadian sample of LSS patients undergoing ESI conservative therapy.

Test-retest reliabilities of 0.87 and 0.91 as measured by the intra-class correlation coefficient (ICC) for the symptom severity and physical function scales respectively, are both above 0.75, indicating excellent reproducibility (Fleiss, 1986). The results compare well with the test-retest reliability of the French version of the Quebec Back Pain Disability Scale by Kopec *et al.* (1995), which reported an ICC of 0.88 on a sample of 46 patients.

Measures of internal consistencies for the overall scales of symptom severity, physical function, and satisfaction over the study period were all above the acceptability level of 0.65 (Cronbach's Coefficient α) (Nunnally, 1978) indicating good internal

consistency. Results after baseline produced high internal consistencies ranging from 0.82 for the symptom severity scale, to 0.97 for the satisfaction scale. The neuroischemic domain of the symptom severity scale revealed lower internal consistency throughout the study period, which is what contributed to an acceptable, but lower than expected overall internal consistency for the symptom severity scale. Stucki and colleagues (1996) found similar lower internal consistencies for the neuroischemic domain of their English version LSS symptom severity scale. As commented by Stucki *et al.* (1996), an addition of questions to the neuroischemic domain might increase the internal consistency of the domain and the overall scale itself because Cronbach's α increases with increasing number of items (Cronbach, 1951). It was interesting to note that the LSS scales were all more internally consistent than the physical component of the SF-36 (α range, 0.56 to 0.63), but less internally consistent than the QBPDS (α range, 0.91 to 0.93). The latter comparison may partly reflect the fact that the QBPDS has many more items than each of the LSS scales and that it is limited to a more specific health domain (back pain) than is the SF-36 or the LSS physical function scale.

Validation of the LSS physical function scales with the physical components of the SF-36 and QBPDS revealed strong associations as hypothesized. Both of these scales measure functional status through their respective measures of physical disability and, thus, were suitable for assessing the concurrent validity of the French language LSS scale. As expected, the symptom severity scale was found to moderately correlate with the QBPDS. Questions on the QBPDS were asked in the form: "Today, do you find it difficult to perform the following activities because of your back?". Thus, the finding that the overall symptom severity measure was found to correlate only moderately with QBPDS, is likely due to the fact that symptom severity can only contribute to difficulty, but cannot be equated with difficulty. Other factors that could contribute to difficulty are self-perceived capability, self-efficacy, physical disability, and neuroischemic deficits. For this reason, a moderate correlation was found between the QBPDS and the neuroischemic domain of the LSS symptom severity scale.

Comparisons of the LSS satisfaction scale scores on patients' responses regarding effectiveness of ESI, demonstrated that this specific instrument was a valid measure. Statistically significant differences were found at one and three months between the mean

LSS satisfaction scale scores for those answering 'yes' and 'no' to a specific question regarding satisfaction with the injection relieving pain. A statistically significant difference in the satisfaction scale score among patients answering 'yes and 'no' to a specific question pertaining to whether the back injection would be chosen again, was found at three months, but not at one month. Weaker association at one month is probably due to the fact that most patients had only received one injection at the assessment period of one month. Thus, it is possible that the number of injections were not enough for a patient to decide whether he or she would have the injection again. Therefore, at one month this question was not a good indicator of satisfaction. Overall, the satisfaction scale was found to adequately discriminate between those that did and did not find the ESI to be an effective therapy.

Determining responsiveness to change of an instrument is difficult in a patient sample where not all patients are guaranteed to improve and where a well established criterion to identify those who do and who do not improve is not present (Fortin *et al.*, 2000). In this study, patient responses related to their satisfaction were used as an external criterion of change. Following the approach of Fortin *et al.* (2000), responsiveness of the LSS symptom severity and physical function scales were assessed separately for patients who were satisfied and those who were not. The results showed high discrimination between those satisfied and unsatisfied. Both SRM and ES indicated moderate to high responsiveness in those satisfied, while for unsatisfied patients SRM and ES values were close to zero or positive, indicating no change or some worsening of the condition.

The psychometric study was limited in certain respects. First, the questionnaires were not 'self-administered', but rather were completed with the aid of a research assistant. Retest data was obtained over the phone, although patients were given the questionnaires before hand, which they used to follow along with as the research assistant conducted the telephone interview. Thus, the interviewer was present and aided in the completion of the questionnaires at both test and re-test times. This could be a potential source for interview bias, but considering that help was given at both test and re-test time, bias would have been similar at both time 1 and time 2. Even though aid was given to patients in filling out the questionnaires, it still only took patients approximately five

minutes to complete. Second, because the sample was restricted to a predominately white French-Canadian population, the findings may not be generalizable to French speakers in a different culture. The LSS scales must be tested and adapted using cross-cultural validation standards (Bullinger *et al.*, 1993; Guillemin *et al.*, 1993; Guyatt, 1993) in order that they be applicable in other languages and cultures. Third, the study used ordinal Likert response formats following Stucki *et al.* (1996), thus care should be taken when interpreting the results of the parametric analyses (Merbitz *et al.*, 1989; Silverstein *et al.*, 1992).

The LSS symptom severity, physical function and satisfaction scales can be used to complement existing measures of back pain disability and overall health status. These scales are specific to lumbar spinal stenosis and when used as primary outcomes can serve as useful indicators of improvement in clinical trials of treatment for this condition. The LSS scales can be used in their original form, regardless of the type of intervention being evaluated. The satisfaction scale can be modified to assess other conservative therapies on lumbar spinal stenosis by replacing the word 'injection' with another specific conservative therapy or with the word 'treatment'.

The psychometric properties of the LSS-specific scales show that the French language adaptations of these scales, originally developed by Stucki *et al.* (1996), are reliable, valid, internally consistent and responsive to change. As such, they may be used as primary outcomes in clinical studies assessing potential treatment modalities for LSS patients. Therefore, use of the French language LSS scales as primary outcomes in the analysis of the randomized control trial assessing ESI efficacy in LSS patients is justified. No previous studies have used LSS-specific validated outcome measures for assessing improvement from ESI.

This thesis reports on the analysis of what appears, based on the literature review from Chapter 2, to be the first prospective randomized control trial to assess the effectiveness of ESI treatment exclusively in LSS patients. An advantage of this study compared to previous ones relates to the use of a multivariable repeated measures analysis which allowed me to take into account that the same outcomes were assessed repeatedly at 1, 2, and 3 months. The simultaneous analyses of the outcomes observed at three subsequent visits were instrumental in increasing statistical power of the test of the

treatment effect, allowing the detection of marginally significant yet clinically relevant improvements. Another advantage of the repeated measures analysis was that it permitted formal testing of the hypothesis that the treatment effect remains constant during the first three months after the initial injection.

The results of this study indicate that patients administered epidural steroid injection therapy for LSS will experience a marginally significant decrease in symptom severity and will display improved functional capacity over a three month period. These findings support previous uncontrolled studies, which showed ESI to have a beneficial effect on reducing pain (Ciocon *et al.*, 1994), and improving physical function (Hoogmartens & Morelle, 1987). Radu & Menkes (1998) found the treatment effect to last 2-3 months, while Ciocon *et al.* (1994) found a significant reduction in pain at 2 months after initial injection, with the effect lasting up to ten months. The results of this study indicate that improvement lasts at least up until three months, with a trend for the treatment effect to decrease over time. The treatment effect was not found to be statistically significant at 6 or 12 months, although the smaller sample size at these longer follow-up periods limits the interpretability of these results.

Following the original protocol, the main outcome of this study was assessed in an overall sample of patients with LSS at three months follow-up. However, identification of a statistically very significant interaction between treatment and high blood pressure suggests a different interpretation of the above results. Closer examination of the results reveals that the treatment effect varies substantially depending on the presence/absence of the history of treatment for HBP. LSS patients with a history of being treated for high blood pressure will not experience a decrease in symptom severity or improved physical function from ESI therapy, compared to placebo. On the other hand, LSS patients without high blood pressure will experience a definitely statistically significant improvement over three months when treated with ESI. Those without high blood pressure will also exhibit significantly greater satisfaction from ESI treatment.

High blood pressure as a potential effect modifier of the effect of ESI treatment has not been reported in previous literature, but *a posteriori* may be considered clinically plausible. This dramatic difference in treatment benefit may be explained by the possible

interplay between the neurologic (Findlay, 2000) and vascular (Porter, 2000) compression theories. The neurologic compression theory states that the nerve root or cauda equina may be affected by compression, stretching and inflammation (Findlay, 2000). It is likely that the cortisone in the epidural injections work neurologically, by relieving this inflammation at the lumbar nerve root (Lindahl & Rexed, 1951; Barry & Kendall, 1962). The vascular compression theory explains that the presence of spinal stenosis can also compromise normal vascular blood flow to the cauda equina (Porter, 2000). High blood pressure would further jeopardize blood flow to this area, so much so that it might override the benefits received from ESI, thus resulting in the absence of an overall benefit from treatment. Those without high blood pressure would not have this additional compromised blood flow to the spine, thus enabling the steroid to take effect by reducing inflammation. Thus, HBP and its effect on the vascular blood flow in the spine might override the neurologic benefits received from the epidural steroid injection. The fact that the treatment-HBP interaction was statistically very significant for all LSS scales as well as for the 'generic' back pain scale (QBPDS) indicates the robustness of this finding and gives empirical support to the above conjecture. However, it should be emphasized that the dependence of the ESI treatment effect on the presence of HBP was not postulated *a priori* in the study protocol. This increases the risk of a type I error and makes it essential to confirm this finding in an independent study.

The study is limited in certain respects. First, there is no current gold standard for the definition and diagnosis of lumbar spinal stenosis. It is possible that not all patients included in this study have spinal stenosis. To address this issue, the study protocol specified strict clinical inclusion and exclusion criteria. These criteria were based on a standardized and generalizable definition of LSS previously applied to identify candidates in prospective studies of surgical interventions and conservative therapies for LSS conducted by Katz *et al.* (1995). For example, patients who exhibited moderate to severe pain at rest were excluded since this was not a sign of neurogenic claudication, which is thought by most specialists to be a definite inclusion criterion for LSS. Moreover, additional radiologic data in the form of CT or MRI was collected for each patient to reconfirm the clinical diagnosis of LSS. Very few previous studies have confirmed a clinical LSS diagnosis with radiologic information. Thus, despite a lack of

gold standard for the definition and diagnosis of LSS, considerable efforts were made to maximize the probability that study participants really have LSS. Second, the lack of a large sample and use of a homogenous population from a single centre limited the statistical power and might reduce the external validity of the results. This study does not provide conclusive evidence regarding the persistence of treatment benefit beyond 3 months. On one hand, at the 6 and 12-month analyses, patients remaining in the study represented now a non-random selection of patients whose code was not broken. This could have lead to a differential bias, which might have artificially overestimated the treatment effect at 6 and 12 months, although ESI benefit at this time was already statistically definitely non-significant. One the other hand, the non-significance of the 6- and 12-month effects might be partly due to low statistical power, given reduced sample size. Third, the sub-analysis of HBP patients within the study is limited in several respects. Because HBP was not hypothesized *a priori* as an effect modifier, and because of the inability of conducting further cardiovascular risk sub-analyses due to small sample size, future independent studies of ESI efficacy in larger populations of LSS patients with and without HBP are needed. Moreover, since HBP was not selected *a priori*, the investigators did not collect additional clinical information such as the duration and severity of HBP, which might have helped quantify this exposure more accurately.

This study shows that symptom severity and physical function of LSS patients will improve when given ESI treatment, with the effect lasting at least three months after the first injection. However, the treatment benefit seems to be limited to patients who are not being treated for high blood pressure. These patients will also exhibit significantly greater satisfaction from ESI treatment. Patients with high blood pressure are unlikely to experience a beneficial effect from ESI treatment. Thus, while these results support the use of ESI in patients without hypertension, specialists should be aware of this effect modification when considering ESI therapy as an option for their LSS patients who are also being treated for high blood pressure.

CHAPTER 7: CONCLUSION

The psychometric properties of the French language LSS-specific scales assessing symptom severity, physical function, and satisfaction are reliable, valid and responsive to change. As such, they may be used as primary outcomes in clinical studies assessing potential treatment modalities for LSS patients. The use of these primary outcomes in a randomized controlled trial assessing ESI efficacy in LSS patients found improved symptom severity and physical function over at least three months after the first injection. However, the treatment benefit seems to be limited to LSS patients not on treatment for high blood pressure.

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APPENDIX 1: ETHICS APPROVAL AND CONSENT FORMS

Comités de la Recherche et d'Éthique du
Centre hospitalier universitaire de
l'Université de Montréal

FORMULE DE CONSENTEMENT

Imprimer la plaque du patient ci-dessus

TITRE DU PROJET : Étude contrôlée et randomisée sur l'usage des injections épidurales de stéroïdes dans la sténose spinale lombaire

INVESTIGATEUR PRINCIPAL : Luc Fortin, M.D.

REPRÉSENTANT(S) : Luc Fortin, M.D.
: Francine Bujold, assistante de recherche

BUTS :

Nous désirons obtenir votre autorisation afin de vous faire participer à une étude scientifique. Le but de cette étude est d'évaluer les résultats des injections épidurales de stéroïdes (cortisone) chez les patients atteints de sténose spinale lombaire.

PROCÉDURES:

En acceptant de participer à l'étude, vous recevrez une injection épidurale de stéroïdes ou de soluté physiologique. L'attribution du traitement se fera au hasard. Les méthodes, ainsi que les doses de stéroïdes prescrites pour les injections épidurales dans cette étude, seront identiques à celles utilisées de routine en clinique pour ce genre de procédure.

Vous serez examiné(e) par un médecin avant chaque injection. Un maximum de cinq visites est a prévoir suite à la première injection (1, 2, 3, 6 et 12 mois plus tard) afin d'évaluer votre condition médicale et l'indication de procéder à d'autres injections. De facon régulière, on vous demandera de remplir des questionnaires concernant vos symptômes, vos capacités physiques de même que votre satisfaction suite à votre injection. Vous pourrez omettre de répondre à certaines questions si vous avez des raisons personnelles de le faire.

EFFETS SECONDAIRES:

L'effet secondaire le plus fréquent est un inconfort pendant la procédure. Plus rarement, les effets secondaires suivants peuvent être rencontrés : maux de tête, douleurs au dos d'intensité légère à modérée, nausées et baisses transitoires de la pression artérielle. Ces réactions se produisent généralement de 1 à 10 heures après l'injection, durent quelques heures et disparaissent ordinairement dans les 24 heures. Toutes les autres complications possibles surviennent dans moins de 1% des cas (infections locales, suppression transitoire de la sécrétion endogène de stéroïdes).

CONFIDENTIALITÉ :

Nous assurerons la confidentialité de votre dossier en vous identifiant par un numéro de code au lieu de votre nom. La liste maîtresse sera conservée en lieu sûr. Les personnes qui liront les questionnaires, en particulier vos médecins, ne pourront identifier vos réponses.

BÉNÉFICES:

Il n'y aura pas de bénéfices directs résultants de votre participation.

PROCÉDURES ALTERNATIVES:

Les épidurales sont utilisées de routine dans le traitement des maux de dos. Les usages d'analgésiques (anti-douleurs) et d'anti-inflammatoires seront limités aux comprimés d'acétaminophène (ATASOL[MD], TYLENOL[MD]) fournis par les chercheurs. Toutes les autres formes de thérapies seront acceptées et devront être rapportées. Vous avez le droit de refuser de participer à cette étude. Si vous acceptez de participer, vous pourrez vous retirer à n'importe quel moment, après avoir avisé les chercheurs de votre décision. Quelle que soit votre décision, les soins que vous recevrez ne dépendront aucunement de votre participation à l'étude.

INFORMATION :

Pour toute information concernant cette étude, vous pouvez rejoindre Francine Bujold assistante de recherche 514-281-6000 poste 8245 ou le Dr Luc Fortin, physiatre, responsable de l'étude au 514-527-4155.

J'ai expliqué en détail les buts de l'étude, les procédures ainsi que les complications possibles. J'ai demandé au patient si d'autres explications étaient nécessaires et j'ai procédé à ces explications.

_____ _____

DATE **INVESTIGATEUR**

Je suis informé(e) des buts de l'étude, des procédures prévues ainsi que des effets secondaires possibles. J'ai eu une description détaillée des bénéfices et des procédures alternatives possibles. En signant cette formule de consentement, j'accepte de participer à cette étude et comprends que je suis libre de retirer mon consentement et de me retirer de l'étude à n'importe quel moment. Je comprends aussi que si j'ai besoin d'autres explications, elles me seront fournies.

_____ X_____

DATE **PATIENT(E)**

_____ X_____

DATE **TÉMOIN**

CONSENT FORM

Title of project : Randomized and controlled study regarding the use of steroidal injections in lumbar spinal stenosis

Principal Investigator : Luc Fortin, M.D.

Representative(s) : Luc Fortin, M.D.
Francine Bujold

OBJECTIVES :

We hereby wish to obtain your authorization for your participation in a scientific study. The purpose of this study is to evaluate the effect of steroidal epidural injections (cortisone) on patients suffering from lumbar spinal stenosis.

PROCEDURES :

By accepting to participate in this study, you will receive one steroidal epidural injection or one injection of a physiological solution. The methods as well as the prescribed steroidal doses of the epidural injections in this study, shall be identical to those routinely administered under clinical therapy.

You shall be examined by a doctor before each injection. A maximum of 5 visits will be scheduled following the first injection (1, 2, 3, 6 and 12 months later) in order to evaluate your medical condition and determine whether to proceed with further injections. You will regularly be requested to complete a questionnaire regarding your symptoms, your physical capabilities and your satisfaction following your injection. You are not obligated, should you not wish to for personal reasons to respond to all the questions.

SIDE EFFECTS :

The most common side effect is some discomfort during the procedure. More rarely, the following side effects may be encountered: headaches, backache from light to moderate intensity, nausea and transitory decrease of blood-pressure. These reactions generally appear within 1 to 10 hours following an injection, last a few hours and normally disappear within 24 hours. Other possible complications occur in less than 1% of the cases (i.e. local infections, transitory suppression of steroidal endogenous secretion).

CONFIDENTIALITY :

We shall ensure complete confidentiality of your case-history by identifying you with a code instead of your name. A master list shall be kept in a safe place. The individuals reading the questionnaires, particularly your doctors, will not be able to identify your answers.

BENEFITS :

There shall be no direct benefits resulting from your participation.

ALTERNATIVE PROCEDURES :

The epidurals are routinely used in the treatment of backaches. The use of analgesics (anti-pain) and anti-inflammatories shall be limited to acetaminophen tablets (Atasol[MD], Tylenol[MD]) provided by the researchers. Any other form of therapy will be accepted and should be reported and noted in your file. You have the right to refuse participation in this study. If you accept to participate, you may withdraw at any time, after advising the researchers of such a decision.

Regardless of the decision you partake, the medical care you will receive shall in no way, depend on your participation in the study.

INFORMATION :

For any information regarding this study, please contact Francine Bujold,at 514-281-6000, extension 8245 or Dr. Luc Fortin, physiatrist, responsible for this study, at 514-527-4155.

I have explained in details, the objectives of the study, the procedures as well as the possible complications. I asked the patient if any other explanations were necessary and gave such explanations.

_____ _____

Date Investigator

I have been informed of the objectives of the study, the foreseen procedures as well as the possible side effects. I was given a detailed description of the benefits and the possible alternative procedures. By signing this agreement, I accept to participate in this study and understand that I can withdraw from this study at any time. I also understand that if I shall need further explanations, such explanations shall be provided.

_____ _____

Date Patient

_____ _____

Date Witness

APPENDIX 2: QUESTIONNAIRES

Étude sur l'usage des injections épidurales de stéroïdes dans la sténose spinale

PREMIÈRE ÉVALUATION

Date: _____-_____-_____
Jour Mois An

ND: _____

NE: _____

VISITE: _____

VEUILLEZ LIRE CE QUI SUIT AVANT DE RÉPONDRE au questionnaire.

Nous désirons vous remercier pour votre participation à cette étude. Vous trouverez ci-dessous une série de questions concernant vos problèmes, la façon dont ils affectent votre vie quotidienne et comment vous l es supportez. Il n'y a pas de bonne ou de mauvaise réponse à chacune des questions.

Même s'il est **TRÈS IMPORTANT** pour nous que vous **RÉPONDIEZ À TOUTES LES QUESTIONS,** vous pouvez ignorer l'une ou l'autre si vous avez des raisons personnelles de le faire.

Si vous avez des doutes de la façon dont il faut répondre à l'une des questions, s.v.p. veuillez donner la meilleure réponse possible et inscrivez alors un commentaire **dans la marge**.

1. Imaginez une échelle de 0 à 10 qui indiquerait le degré de votre DOULEUR, 0 représentant aucune douleur et 10, une douleur extrême. Sur cette échelle, estimez votre DOULEUR au cours de la DERNIÈRE SEMAINE. (Encerclez un chiffre de 0 à 10)

0	1	2	3	4	5	6	7	8	9	10

Aucune Extrême

2. AU COURS DU DERNIER MOIS, comment votre douleur vous a-t-elle affecté(e) lorsque vous étiez debout ? (Encerclez la réponse qui vous décrit le mieux)

   1. Je peux rester debout pendant des heures, sans douleur
   2. Je peux rester debout pendant des heures, mais j'ai des douleurs
   3. Je ne peux rester debout plus d'une heure à cause de mes douleurs
   4. Je ne peux rester debout plus de dix minutes à cause de mes douleurs
   5. Je peux à peine rester debout à cause de mes douleurs
   6. Aucune de ces réponses

Date: _____

NE: _____

3. QU'EST-CE QUI VOUS DÉRANGE LE PLUS : les douleurs au dos et aux fesses ou les douleurs aux jambes ? (Encerclez la réponse qui vous décrit le mieux)

   1. Beaucoup plus les douleurs au dos et aux fesses que celles aux jambes
   2. Un peu plus les douleurs au dos et aux fesses que celles aux jambes
   3. Autant les douleurs au dos et aux fesses que celles aux jambes
   4. Un peu plus les douleurs aux jambes que celles au dos et aux fesses
   5. Beaucoup plus les douleurs aux jambes que celles au dos et aux fesses

VEUILLEZ RÉPONDRE À CHACUNE DES QUESTIONS SUIVANTES en encerclant la réponse qui vous décrit le mieux

4. Quel groupe représente votre revenu brut (et celui de votre époux(se)) pour la dernière année ? (Encerclez un seul chiffre)

   1. Moins de 14 999 $ par année
   2. 15 000 $ - 29 999 $ par année
   3. 30 000 $ - 49 999 $ par année
   4. Plus de 50 000 $ par année
   5. Je ne sais pas

5. Combien d'année(s) de scolarité avez-vous ?

   _____ année(s).

6. Avez-vous obtenu un diplôme d'études : (Cocher votre réponse)

	Oui	Non
1. Primaire	( )	( )
2. Secondaire	( )	( )
3. Collégial	( )	( )
4. Universitaire	( )	( )

7. Quel est votre mode de vie présentement ? (Encerclez la réponse qui vous décrit le mieux)

   1. Je vis seul(e)
   2. Je vis avec mon époux(se)
   3. Je vis avec d'autres membres de ma famille ou des amis
   4. Je vis dans une maison de retraite ou une maison de santé
   5. Autre (spécifiez _____)

Date: _____

NE: _____

8. Veuillez encercler tout appareil dont vous avez eu besoin au cours DU DERNIER MOIS.

1. Aucun
2. Canne/béquille
3. Marchette
4. Chaise roulante

AVEZ-VOUS REMARQUÉ si vos douleurs sont soulagées en :
(Veuillez encercler une réponse à chacune des questions)

	Jamais	Quelquefois	Habituellement	Toujours
9. vous penchant vers l'avant ?	0	1	2	3
10. marchant ?	0	1	2	3
11. vous assoyant ?	0	1	2	3

12. VEUILLEZ NOTER TOUS **LES MÉDICAMENTS** que vous prenez **ACTUELLEMENT**, ainsi que leurs **DOSAGES** (incluant les médicaments que vous prenez seulement au besoin).

Médication **À quelle fréquence**

_____

_____

_____

_____

_____

Date: _____

NE: _____

QU'ATTENDEZ-VOUS de votre injection épidurale ?
(Veuillez encercler une réponse à chacune des questions)

Je m'attends à ce que l'injection épidurale.....	Improbable	Très peu probable	Possiblement	Très probable	Plus que probable
13. soulage mes douleurs au dos aux fesses ou aux jambes	1	2	3	4	5
14. soulage mes douleurs aux jambes	1	2	3	4	5
15. soulage mes picotements et mes engourdissements	1	2	3	4	5
16. me donne un meilleur équilibre et plus de sûreté dans ma démarche	1	2	3	4	5
17. me rende capable d'exécuter une plus grande partie de mes tâches domestiques ou travaux extérieurs	1	2	3	4	5
18. me rende capable de participer à plus d'activités récréatives ou sportives, ou de prendre de longues marches	1	2	3	4	5
19. me rende capable de dormir plus confortablement	1	2	3	4	5

Date: _____

NE: _____

QUELLE IMPORTANCE ont pour vous les <u>résultats suivants</u> ?
(Veuillez encercler une réponse à chacune des questions)

Est-ce important que l'injection épidurale.....	Pas important	Peu important	Modérément important	Très important	Extrêmement important
20. soulage mes douleurs au dos et/ou aux fesses	1	2	3	4	5
21. soulage mes douleurs aux jambes	1	2	3	4	5
22. soulage mes picotements et engourdissements	1	2	3	4	5
23. me donne un meilleur équilibre et plus de sûreté dans ma démarche	1	2	3	4	5
24. me rende capable d'exécuter une plus grande partie de mes tâches domestiques ou travaux extérieurs	1	2	3	4	5
25. me rende capable de participer à plus d'activités récréatives ou sportives, ou de prendre de longues marches	1	2	3	4	5
26. me rende capable de dormir plus confortablement	1	2	3	4	5

Date: _____

NE: _____

Les questions suivantes concernent les SERVICES, TESTS, VISITES AU BUREAU DU MÉDECIN et autres EXPÉRIENCES que vous avez eues au COURS du DERNIER MOIS. (Veuillez encercler une réponse pour CHAQUE QUESTION)

27. Avez-vous déjà reçu une injection épidurale dans le passé ?

0. Non Passez à la question 28.
1. Oui

Si oui, était-ce pour votre problème de dos actuel (sténose spinale) ?

0. Non Passez à la question 28.
1. Oui

Si oui, combien d'injection(s) et à quel moment ? _____

_____

_____

28. Au cours DU DERNIER MOIS, combien de VISITES AU BUREAU DU MÉDECIN avez-vous faites pour vos problèmes de dos?

_____ visites

29. Au cours DU DERNIER MOIS, avez-vous reçu la VISITE D'UNE INFIRMIÈRE à domicile pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

30. Au cours DU DERNIER MOIS, avez-vous vu un PHYSIOTHÉRAPEUTE pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

Date: _____

NE: _____

31. Au cours DU DERNIER MOIS, avez-vous vu un ERGOTHÉRAPEUTE pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

32. Au cours DU DERNIER MOIS, avez-vous vu un OSTÉOPATHE pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

33. Au cours DU DERNIER MOIS, avez-vous vu un CHIROPRATICIEN pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

34. Au cours DU DERNIER MOIS, avez-vous vu un MASSOTHÉRAPEUTE pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

35. Au cours DU DERNIER MOIS, avez-vous vu un spécialiste en ACUPUNCTURE pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

Date: _____

NE: _____

36. Au cours DU DERNIER MOIS, avez-vous assisté à une CLASSE DE DOS pour vos problèmes de dos ?

0. Non
1. Oui

Si oui, combien de visites par semaine ?_____ ; et pendant combien de semaine(s) ?____

37. Au cours DU DERNIER MOIS, avez-vous porté un CORSET pour votre dos ?

0. Non
1. Oui

38. Au cours DU DERNIER MOIS, avez-vous reçu des traitements avec TENS (neurostimulateur transcutané) pour votre dos ?

0. Non
1. Oui

39. AU COURS DU DERNIER MOIS, combien de fois vous a-t-on hospitalisé(e) ?

_____ Hospitalisation(s)

Veuillez noter la(les) raison(s) pour chacune des hospitalisations, le nom de l'hôpital et le nombre de jours où vous avez été hospitalisé(e)

Nom de l'hôpital	**Raison de l'admission**	**Nombre de jours**

Étude sur l'usage des injections épidurales de stéroïdes dans la sténose spinale

1 - 2 - 3 - 6 - 12 MOIS

Date: _____-_____-_____
An Mois Jour

ND: _____

NE: _____

VEUILLEZ LIRE CE QUI SUIT AVANT DE RÉPONDRE au questionnaire.

Nous désirons vous remercier pour votre participation à cette étude. Vous trouverez ci-dessous une série de questions concernant vos problèmes, la façon dont ils affectent votre vie quotidienne et comment vous les supportez. Il n'y a pas de bonne ou de mauvaise réponse à chacune des questions.

Même s'il est **TRÈS IMPORTANT** pour nous que vous **RÉPONDIEZ À TOUTES LES QUESTIONS**, vous pouvez ignorer l'une ou l'autre si vous avez des raisons personnelles de le faire.

Si vous avez des doutes sur la façon dont il faut répondre à l'une des questions, veuillez donner la meilleure réponse possible et inscrivez alors un commentaire dans **la marge**.

1. Imaginez une échelle de 0 à 10 qui indiquerait le degré de votre DOULEUR, 0 représentant aucune douleur et 10, une douleur extrême. Sur cette échelle, estimez votre DOULEUR au cours de la DERNIÈRE SEMAINE? (Encerclez inscrivez un chiffre de 0 à 10)

0	1	2	3	4	5	6	7	8	9	10

Aucune Extrême

2. AU COURS DU DERNIER MOIS, comment votre douleur vous a-t-elle affecté(e) lorsque vous étiez debout? (Encerclez la réponse qui vous décrit le mieux)

   1 Je peux rester debout pendant des heures, sans douleur
   2. Je peux rester debout pendant des heures, mais j'ai des douleurs
   3. Je ne peux rester debout plus d'une heure à cause de mes douleurs
   4. Je ne peux rester debout plus de dix minutes à cause de mes douleurs
   5. Je peux à peine rester debout à cause de mes douleurs
   6. Aucune de ces réponses

Date: _____

NE: _____

3. QU'EST-CE QUI VOUS DÉRANGE LE PLUS: les douleurs au dos et aux fesses ou les douleurs aux jambes? (Encerclez la réponse qui vous décrit le mieux)

   1. Beaucoup plus les douleurs au dos et aux fesses que celles aux jambes
   2. Un peu plus les douleurs au dos et aux fesses que celles aux jambes
   3. Autant les douleurs au dos et aux fesses que celles aux jambes
   4. Un peu plus les douleurs aux jambes que celles au dos et aux fesses
   5. Beaucoup plus les douleurs aux jambes que celles au dos et aux fesses

AVEZ-VOUS REMARQUÉ que vos douleurs étaient soulagées en:
(Veuillez encercler une réponse à chacune des questions)

	Jamais	Quelquefois	Habituellement	Toujours
4. vous penchant vers l'avant?	0	1	2	3
5. marchant?	0	1	2	3
6. vous assoyant quelques minutes?	0	1	2	3

7. Veuillez encercler tout appareil dont vous avez eu besoin au cours DU DERNIER MOIS.

   1. Aucun
   2. Canne/béquille
   3. Marchette
   4. Chaise roulante

Date: _____

NE: _____

8a. VEUILLEZ NOTER TOUS **LES MÉDICAMENTS** que vous prenez **ACTUELLEMENT**, ainsi que leurs **DOSAGES** incluant les médicaments que vous prenez seulement au besoin.

Médication	À quelle fréquence

8b. Nombre de tylénol depuis la dernière visite: _____

9. COMBIEN D'INJECTIONS dans la colonne vertébrale avez-vous reçues jusqu'à ce jour depuis le début de l'étude? (inclure la première injection)

_____ injections épidurales

_____ autres types d'injections

10. L'injection reçue pour votre sténose spinale a-t-elle SOULAGÉ votre DOULEUR? (Encerclez la réponse qui vous décrit le mieux)

1. Oui, a complètement soulagé la douleur
2. Oui, a soulagé presque complètement la douleur
3. Oui, a soulagé une partie de la douleur
4. Non, n'a pas soulagé la douleur du tout
5. Non, maintenant la douleur est pire

Date: _____

NE: _____

MAINTENANT, nous aimerions savoir si vous êtes SATISFAIT(E) de votre INJECTION.

11. Maintenant que vous avez beaucoup appris concernant les injections pour la sténose spinale, si vous pouviez faire un retour en arrière, choisiriez-vous de recevoir une injection à votre dos? ((Veuillez encercler une réponse)

    1. Oui, définitivement
    2. Oui, probablement
    3. Non, probablement pas
    4. Non, définitivement pas

Les questions suivantes concernent les SERVICES, VISITES AU BUREAU DU MÉDECIN et autres EXPÉRIENCES que vous avez eues au COURS DU DERNIER MOIS.

(Veuillez ENCERCLER une réponse à CHACUNE DES QUESTIONS)

12. Au cours DU DERNIER MOIS, combien de VISITES AU MÉDECIN avez-vous faites pour vos problèmes de dos?

    _____ visites

13. Au cours DU DERNIER MOIS, avez-vous reçu la VISITE D'UNE INFIRMIÈRE à domicile pour vos problèmes de dos?

    0. Non
    1. Oui

    Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?____

14. Au cours DU DERNIER MOIS, avez-vous vu un PHYSIOTHÉRAPEUTE pour vos problèmes de dos?

    0. Non
    1. Oui

    Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?____

Date: _____

NE: _____

15. Au cours DU DERNIER MOIS, avez-vous vu un ERGOTHÉRAPEUTE pour vos problèmes de dos?

0. Non
1. Oui

Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?____

16. Au cours DU DERNIER MOIS, avez-vous vu un OSTÉOPATHE pour vos problèmes de dos?

0. Non
1. Oui

Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?____

17. Au cours DU DERNIER MOIS, avez-vous vu un CHIROPRATICIEN pour vos problèmes de dos?

0. Non
1. Oui

Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?____

18. Au cours DU DERNIER MOIS, avez-vous vu un MASSOTHÉRAPEUTE pour vos problèmes de dos?

0. Non
1. Oui

Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?____

19. Au cours DU DERNIER MOIS, avez-vous vu un spécialiste en ACUPUNCTURE pour vos problèmes de dos?

0. Non
1. Oui

Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?____

Date: _____

NE: _____

20. Au cours DU DERNIER MOIS, avez-vous assisté à une CLASSE DE DOS pour vos problèmes de dos?

0. Non
1. Oui

Si oui, combien de visites par semaine?____ ; et pendant combien de semaine(s)?_____

21. Au cours DU DERNIER MOIS, avez-vous porté un CORSET pour votre dos?

0. Non
1. Oui

22. Au cours DU DERNIER MOIS, avez-vous reçu des traitements avec TENS (neurostimulateur transcutané) pour votre dos?

0. Non
1. Oui

23. AU COURS DU DERNIER MOIS, combien de fois vous a-t-on hospitalisé(e)?

_____ Hospitalisations

Veuillez noter la(les) raison(s) pour chacune des hospitalisations, le nom de l'hôpital et le nombre de jours où vous avez été hospitalisé(e)

Nom de l'hôpital	**Raison de l'admission**	**Nombre de jours**

Date: _____

NE: _____

VISITE: ____

SSP1

ÉCHELLE DE SÉVÉRITÉ DES SYMPTÔMES

1. Décrivez-nous la **DOULEUR** que vous avez ressentie en moyenne AU COURS DU DERNIER MOIS, incluant toutes douleurs au **DOS**, aux **FESSES**, ainsi que les douleurs **DESCENDANT DANS LES JAMBES.**
   (Veuillez encercler une réponse)

   0. Aucune
   1. Légère
   2. Modérée
   3. Intense
   4. Très intense

2. Décrivez-nous la **DOULEUR** que vous avez ressentie AU COURS DU DERNIER MOIS dans votre **DOS** ou **VOS FESSES**.
   (Veuillez encercler une réponse)

   0. Aucune
   1. Légère
   2. Modérée
   3. Intense
   4. Très intense

3. Décrivez-nous la **DOULEUR** que vous avez ressentie AU COURS DU DERNIER MOIS dans vos **JAMBES** ou **VOS PIEDS**.
   (Veuillez encercler une réponse)

   0. Aucune
   1. Légère
   2. Modérée
   3. Intense
   4. Très intense

Date: _____

NE: _____

VISITE: ____

4. Décrivez-nous les **ENGOURDISSEMENTS** ou **PICOTEMENTS** que vous avez ressentis AU COURS DU DERNIER MOIS dans vos **JAMBES** ou **VOS PIEDS.**
(Veuillez encercler une réponse)

   0. Aucune
   1. Légère
   2. Modérée
   3. Intense
   4. Très intense

5. AU COURS DU DERNIER MOIS, décrivez-nous la **FAIBLESSE** dans vos **JAMBES** ou **VOS PIEDS.**
(Veuillez encercler une réponse)

   0. Aucune
   1. Légère
   2. Modérée
   3. Intense
   4. Très intense

6. AU COURS DU DERNIER MOIS, à quelle **FRÉQUENCE** avez-vous ressenti des **DOULEURS** au **DOS**, aux **FESSES** ou **AUX JAMBES**.
(Veuillez encercler une réponse)

   0. Jamais
   1. Moins d'une fois par semaine
   2. Au moins une fois par semaine
   3. Tous les jours pendant au moins quelques minutes
   4. Tous les jours pendant la plus grande partie de la journée
   5. Chaque minute de la journée

7. AUCOURS DU DERNIER MOIS, avez-vous eu des **PROBLÈMES D'ÉQUILIBRE**.
(Encerclez la réponse qui vous décrit le mieux)

   0. Non, je n'ai pas eu de problème d'équilibre
   1. Oui, quelquefois, j'ai manqué d'équilibre ou ma démarche a manqué d'assurance.
   2. Oui, souvent, j'ai manqué d'équilibre ou ma démarche a manqué d'assurance.

Date: _____

NE: _____

VISITE: ____

CAPACITÉ À LA MARCHE

1. AU COURS DU DERNIER MOIS, lors d'une journée typique, quelle **DISTANCE** avez-vous marché ?
   (Encerclez la réponse qui vous décrit le mieux)

   1. Plus de deux milles (3 km)
   2. Plus d'un mille (1.5 km), mais moins de deux milles (3 km)
   3. Plus de deux coins de rues, mais moins d'un mille (1.5 km)
   4. Plus de cinquante pieds (15 mètres), mais moins de deux coins de rues
   5. Moins de cinquante pieds (15 mètres)

2. AU COURS DU DERNIER MOIS, avez-vous :
   (Veuillez encercler une réponse à chacune des questions)

	Oui, sans problème	Oui, mais parfois avec de la douleur	Oui, mais souvent avec de la douleur	Oui, mais toujours avec de la douleur	Non, incapable de le faire
A. Marché à l'extérieur ou dans des centres d'achats pour votre plaisir ?	1	2	3	4	5
B. Magasiné pour votre épicerie ou d'autres achats ?	1	2	3	4	5
C. Marché dans les différentes pièces de votre maison ou appartement ?	1	2	3	4	5
D. Marché de votre chambre à la salle de bain ?	1	2	3	4	5

Date: _____

NE: _____

VISITE: ____

ÉCHELLE DE SATISFACTION

1. MAINTENANT, nous aimerions savoir si vous êtes SATISFAIT(E), de votre injection.

   À QUEL POINT êtes-vous **SATISFAITE(E)** suite à votre **INJECTION** au dos ?
   (Veuillez encercler une réponse à chacune des questions)

	Très satisfait(e)	Passablement satisfait(e)	Passablement insatisfait(e)	Très insatisfait(e)
A. Des résultats dans l'ensemble ?	1	2	3	4
B. Du soulagement de vos engourdissements et picotements ?	1	2	3	4
C. Du soulagement de votre douleur ?	1	2	3	4
D. De votre capacité à marcher confortablement ?	1	2	3	4
E. De votre capacité à accomplir les tâches domestiques, autour de la maison ou au travail ?	1	2	3	4
F. De la force dans vos cuisses, vos jambes et vos pieds ?	1	2	3	4
G. De votre équilibre, de l'assurance de votre démarche ?	1	2	3	4

DATE: _____

NE: _____

ÉCHELLE D'INCAPACITÉ

RÉSULTANT DE

DOULEURS ~~DORSALES~~

UTILISÉE AU QUÉBEC

DATE: _____

NE: _____

Ce questionnaire porte sur la façon dont votre douleur au dos affecte votre vie de tous les jours. Les personnes souffrant de maux de dos trouvent parfois difficile d'entreprendre certaines activités quotidiennes. Nous aimerions savoir si vous éprouvez de la difficulté à accomplir les tâches énumérées ci-dessous en raison de votre douleur au dos. Veuillez encercler le chiffre de l'échelle de 0 à 5 qui correspond le mieux à chacune des activités (sans exception).

Eprouvez-vous de la difficulté aujourd'hui à accomplir les activités suivantes en raison de votre douleur au dos?

	Aucune difficulté	Très peu difficile	Un peu difficile	Difficile	Très difficile	Incapable
1. Sortir du lit	0	1	2	3	4	5
2. Dormir toute la nuit	0	1	2	3	4	5
3. Vous retourner dans le lit	0	1	2	3	4	5
4. Vous promener en voiture	0	1	2	3	4	5
5. Rester debout durant 20 à 30 minutes	0	1	2	3	4	5
6. Rester assis sur une chaise durant plusieurs heures	0	1	2	3	4	5
7. Monter un seul étage à pied	0	1	2	3	4	5
8. Faire plusieurs coins de rue à pied (300 à 400 m)	0	1	2	3	4	5
9. Marcher plusieurs milles	0	1	2	3	4	5
10. Atteindre des objects sur des tablettes assez élevées	0	1	2	3	4	5

DATE: _____

NE: _____

Éprouvez-vous de la difficulté aujourd'hui à accomplir les activités suivantes <u>en raison de votre douleur au dos?</u>

	Aucune difficulté	Très peu difficile	Un peu difficile	Difficile	Très difficile	Incapable
11. Lancer une balle	0	1	2	3	4	5
12. Courir un coin de rue	0	1	2	3	4	5
13. Sortir des aliments du réfrigérateur	0	1	2	3	4	5
14. Faire votre lit	0	1	2	3	4	5
15. Mettre vos bas (collants)	0	1	2	3	4	5
16. Vous pencher pour laver le bain	0	1	2	3	4	5
17. Déplacer une chaise	0	1	2	3	4	5
18. Tirer ou pousser de lourdes portes	0	1	2	3	4	5
19. Transporter deux sacs d'épicerie	0	1	2	3	4	5
20. Soulever et transporter une grosse valise	0	1	2	3	4	5

DATE: _____

NE: _____

MOS Short Form-36 (SF-36)

ÉTAT DE SANTÉ GÉNÉRAL

Ce sondage porte sur ce que vous pensez de votre état de santé. Veuillez répondre à toutes les questions en encerclant le chiffre approprié 1, 2, 3, etc.

1. En GÉNÉRAL, comment évalueriez-vous votre **SANTÉ**?
(n'encerclez qu'un seul chiffre)

   Excellente 1

   Très bonne 2

   Bonne 3

   Passable 4

   Mauvaise 5

2. COMPARATIVEMENT À IL Y A UN AN, comment évaluez-vous votre **SANTÉ** en **GÉNÉRAL MAINTENANT** ?
(n'encerclez qu'un seul chiffre)

   Bien meilleure qu'il y a un an 1

   Un peu meilleure qu'il y a un an 2

   À Peu près la même chose 3

   Un peu moins bonne qu'il y a un an 4

   Beaucoup moins bonne qu'il y a un an . . . 5

DATE: _____

NE: _____

3. **Les questions suivantes portent sur les ACTIVITÉS que vous pourriez faire au cours d'une JOURNÉE TYPIQUE. VOTRE SANTÉ vous limite-t-elle dans ces activités ?**
Si oui, à quel point ?
(Encerclez 1, 2 ou 3 pour chaque activité)

	Oui, limité beaucoup	Oui, limité un peu	Non, pas limité du tout
a. Des activités vigoureuses comme courir, lever des objets lourds, participer à de sports exigeants	1	2	3
b. Des activités modérées, comme bouger une table, pousser une balayeuse, jouer aux quilles, au golf	1	2	3
c. Lever ou transporter des sacs de provisions	1	2	3
d. Monter quelques étages à pied	1	2	3
e. Monter un seul étage	1	2	3
f. Vous pencher ou vous mettre à genoux	1	2	3
g. Marcher plus d'un mille	1	2	3
h. Marcher quelques coins de rue	1	2	3
i. Marcher un coin de rue	1	2	3
j. Prendre votre bain ou vous habiller	1	2	3

DATE: _____

NE: _____

4. AU COURS DES QUATRE DERNIÈRES SEMAINES, avez vous eu l'un ou l'autre des **PROBLÈMES** suivants à votre **TRAVAIL** ou lors de toute autre **ACTIVITÉ QUOTIDIENNE RÉGULIÈRE** et qui était(ent) dû à votre santé physique ?

(Veuillez répondre par OUI ou NON en encerclant le 1 ou le 2 sur chaque ligne)

	OUI	NON
a. Avez-vous diminué la somme de temps que vous passiez au travail ou à vos autres activités ?	1	2
b. Avez-vous accompli moins que vous ne le souhaitiez ?	1	2
c. Avez-vous été limité dans le type de travail ou d'autres activités que vous faisiez ?	1	2
d. Avez-vous de la difficulté à accomplir votre travail ou d'autres activités ? (Par exemple, ils exigeaient un surplus d'efforts)	1	2

5. AU COURS DES QUATRE DERNIÈRES SEMAINES, avez vous eu l'un ou l'autre des **PROBLÈMES** suivants à votre **TRAVAIL** ou lors de toute autre **ACTIVITÉ QUOTIDIENNE RÉGULIÈRE** et qui était(ent) dû à un problème émotif quelconque?

(Veuillez répondre par OUI ou NON en encerclant le 1 ou le 2 sur chaque ligne)

	OUI	NON
a. Avez-vous diminué la somme de temps que vous passiez au travail ou à vos autres activités ?	1	2
b. Avez-vous accompli moins que vous ne le souhaitiez ?	1	2
c. Avez-vous fait votre travail ou vos autres activités moins soigneusement que d'habitude ?	1	2

DATE: _____

NE: _____

6. AU COURS DES QUATRE DERNIÈRES SEMAINES, jusqu'à quel point votre **SANTÉ PHYSIQUE** ou des **PROBLÈMES ÉMOTIFS** ont-ils entravé vos **ACTIVITÉS SOCIALES NORMALES** avec la famille, les amis, les voisins ou le groupe ?

(n'encerclez qu'un seul chiffre)

Pas du tout 1
Légèrement 2
Modérément 3
Passablement 4
Extrêmement 5

DOULEUR

7. Quel **DEGRÉ DE DOULEUR CORPORELLE** avez-vous ressenti au cours des QUATRE DERNIÈRES SEMAINES ?

Aucune douleur 1
Très légère 2
Légère 3
Modérée 4
Sévère 5
Très sévère 6

8. AU COURS DES QUATRE DERNIÈRES SEMAINES, jusqu'à quel point la **DOULEUR** a-t-elle entravé votre **TRAVAIL NORMAL** (tant le travail en dehors de la maison que les travaux domestiques) ?

Pas du tout 1
Légèrement 2
Modérément 3
Passablement 4
Extrêmement 5

DATE: _____

NE: _____

VOS SENTIMENTS

9. **Ces questions portent sur la façon dont vous vous sentez et sur comment les choses ont été pour vous AU COURS DU DERNIER MOIS. Pour chaque question, indiquez une réponse qui est le plus près de la façon dons vous vous êtes senti.**

AU COURS DU DERNIER MOIS ...
(n'encerclez qu'un seul chiffre par ligne)

	Tout le temps	La plupart du temps	Une bonne partie du temps	Une partie du temps	Un peu	Jamais
a. Vous sentiez-vous plein d'énergie ?	1	2	3	4	5	6
b. Avez-vous été une personne très nerveuse ?	1	2	3	4	5	6
c. Avez-vous eu le moral tellement bas que rien ne pouvais vous remonter ?	1	2	3	4	5	6
d. Vous êtes-vous senti calme et l'âme en paix ?	1	2	3	4	5	6
e. Avez-vous eu beaucoup d'énergie ?	1	2	3	4	5	6
f. Vous êtes-vous senti déprimé et l'âme en peine ?	1	2	3	4	5	6
g. Vous êtes-vous senti épuisé?	1	2	3	4	5	6
h. Avez-vous été une personne heureuse ?	1	2	3	4	5	6
i. Vous êtes-vous senti fatigué?	1	2	3	4	5	6

DATE: _____

NE: _____

10. AU COURS DES QUATRE DERNIÈRES SEMAINES, avez-vous été **LIMITÉ** dans vos **ACTIVITÉS SOCIALES** (visiter amis et parenté) par votre **SANTÉ OU DES PROBLÈMES ÉMOTIONNELS**?

(n'encercler qu'un seul chiffre)

Tout le temps 1

La plupart du temps 2

Une partie du temps 3

Un peu 4

Jamais 5

SANTÉ EN GÉNÉRAL

11. Veuillez choisir la réponse qui indique jusqu'à quel point les énoncés suivants sont vrais ou faux dans votre cas.

(n'encerclez qu'un seul chiffre par ligne)

	Définitivement vrai	Vrai la plupart du temp	Incertain	Faux la plupart du temps	Définitivement faux
a. Il me semble que je tombe malade un peu plus facilement que les autres.	1	2	3	4	5
b. Je suis aussi en santé que tous les gens que je connais.	1	2	3	4	5
c. Je m'attends à ce que ma santé se détériore.	1	2	3	4	5
d. Ma santé est excellente.	1	2	3	4	5

DATE. _____

NE: _____

HUI-III MODIFIÉ

1. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **VOIR** assez bien pour lire les **CARACTÈRES** ordinaires dans les **JOURNAUX**?

    1. Je voyais bien sans lunettes ni verres de contact.
    2. Je voyais bien mais je devais utiliser des lunettes ou des verres de contact.
    3. Je ne voyais pas bien, même en utilisant des lunettes ou des verres de contact.
    4. Je ne voyais pas du tout.

2. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **VOIR** assez bien pour **RECONNAÎTRE** un ami de **l'AUTRE CÔTÉ DE LA RUE**?

    1. Je voyais bien sans lunettes ni verres de contact.
    2. Je voyais bien mais je devais utiliser des lunettes ou des verres de contact.
    3. Je ne voyais pas bien, même en utilisant des lunettes ou des verres de contact.
    4. Je ne voyais pas du tout.

3. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **ENTENDRE** se qui se disait au cours d'une **CONVERSATION** avec au moins **TROIS PERSONNES**?

    1. J'entendais ce qui se disait sans prothèse auditive.
    2. J'entendais ce qui se disait mais je devais utiliser une prothèse auditive.
    3. Je n'entendais pas ce qui se disait, même en utilisant une prothèse auditive.
    4. Je n'entendais pas ce qui se disait, mais je n'utilisais pas de prothèse auditive.
    5. Je n'entendais pas du tout.

DATE: _____

NE: _____

4. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **ENTENDRE** se qui se disait au cours d'une **CONVERSATION** avec **UNE SEULE PERSONNE** dans une **PIÈCE SANS BRUIT**?

   1. J'entendais ce qui se disait sans prothèse auditive.
   2. J'entendais ce qui se disait mais je devais utiliser une prothèse auditive.
   3. Je n'entendais pas ce qui se disait, même en utilisant une prothèse auditive.
   4. Je n'entendais pas ce qui se disait, mais je n'utilisais pas de prothèse auditive.
   5. Je n'entendais pas du tout.

5. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **VOUS FAIRE COMPRENDRE** quand **VOUS PARLIEZ**, dans **VOTRE LANGUE**, à des **INCONNUS**?

   1. Je me faisais comprendre complètement.
   2. Je me faisais comprendre en partie.
   3. Je ne me faisais pas comprendre.
   4. Je n'étais pas capable de parler du tout.

6. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **VOUS FAIRE COMPRENDRE** quand **VOUS PARLIEZ** à des **PERSONNES QUI VOUS CONNAISSENT BIEN**?

   1. Je me faisais comprendre complètement.
   2. Je me faisais comprendre en partie.
   3. Je ne me faisais pas comprendre.
   4. Je n'étais pas capable de parler du tout.

DATE: _____

NE: _____

7. AU COURS DES 4 DERNIÈRES SEMAINES, lequel des énoncés suivants vous décrivait le mieux?

   1. Heureux(se) et intéressé(e) par la vie.
   2. Un peu heureux(se).
   3. Un peu malheureux(se).
   4. Très malheureux(se).
   5. Si malheureux(se) que la vie n'en valait pas la peine.

8. AU COURS DES 4 DERNIÈRES SEMAINES, lequel des énoncés suivants décrivait le mieux vos **DOULEURS** et **MALAISES**?

   1. Je n'ai pas eu de douleur ni malaise.
   2. J'ai eu des douleurs ou des malaises d'intensité faible à modérée qui ne m'empêchaient pas d'accomplir mes activités.
   3. J'ai eu des douleurs ou des malaises d'intensité modérée qui m'empêchaient d'accomplir mes activités.
   4. J'ai eu des douleurs ou des malaises d'intensité modérée à sévère qui m'empêchaient d'accomplir mes activités.
   5. J'ai eu des douleurs ou des malaises d'intensité modérée à sévère qui m'empêchaient d'accomplir la plupart de mes activités.

9. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à vous **SOUVENIR DE QUELQUE CHOSE**?

   1. J'étais capable de me rappeler de la plupart des choses.
   2. J'ai eu une tendance à parfois oublier.
   3. J'ai eu une tendance à souvent oublier
   4. J'étais incapable de me rappeler de quoi que ce soit.

DATE: _____

NE: _____

10. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **PENSER** et à **RAISONNER SUR LES PROBLÈMES QUOTIDIENS**?

    1. J'étais capable de raisonner et de résoudre les problèmes quotidiens.
    2. J'avais des difficultés légères à raisonner et à résoudre les problèmes quotidiens.
    3. J'avais des difficultés modérées à raisonner et à résoudre les problèmes quotidiens.
    4. J'avais beaucoup de difficulté à raisonner et à résoudre les problèmes quotidiens.
    5. J'étais incapable de raisonner et de résoudre les problèmes quotidiens

11. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à **MARCHER** et à **COURIR**?

    1. Je pouvais marcher et courir sans limitation.
    2. Je pouvais marcher sans limitation, mais j'étais limité(e) lors de la course.
    3. Je ne pouvais pas marcher plus d'un mille et j'étais incapable de courir.
    4. Je ne pouvais pas marcher plus que quelques coins de rues.
    5. Je ne pouvais pas marcher plus qu'un coin de rue.
    6. Je pouvais marcher seulement dans la maison.
    7. Je ne pouvais pas marcher du tout.

DATE: _____

NE: _____

12. AU COURS DES 4 DERNIÈRES SEMAINES, quelle a été votre **CAPACITÉ** à vous **SERVIR DE VOS MEMBRES SUPÉRIEURS**?

Note: Par MEMBRES SUPÉRIEURS, nous parlons des épaules, bras, mains et doigts.

Note: Par ADAPTATIONS, nous parlons des passe-boutons pour boutonner les vêtements, brosse à dos à long manche, enfile bas, ustensile avec poignée rallongée ou grossie, pince à long manche pour atteindre des objets sur des étagères et autres dispositifs pour aider à accomplir des tâches avec les MEMBRES SUPÉRIEURS.

1. J'ai utilisé mes membres supérieurs sans limitation.

2. J'ai utilisé mes membres supérieurs sans limitation dans des activités modérées telles que racler des feuilles, passer la balayeuse, transporter un sac épicerie ou taper au clavier pour plus d'une heure, mais j'étais limité(e) dans des activités plus rigoureuses.

3. J'ai utilisé mes membres supérieurs sans limitation dans des activités légères mais j'étais limité(e) dans des activités modérées.

4. J'étais limité(e) en utilisant mes membres supérieurs dans des activités légères telles que prendre un bain ou s'habiller, mais je n'ai pas eu besoin d'utiliser des adaptations ou de l'assistance d'une autre personne.

5. J'ai eu besoin d'utiliser des adaptations pour utiliser mes membres supérieurs dans des activités légères telles que prendre un bain ou s'habiller, mais je n'ai pas eu besoin de l'assistance d'une autre personne.

6. J'ai eu besoin de l'assistance d'une autre personne pour toutes les activités nécessitant l'utilisation de mes membres supérieurs.

DATE: _____

NE: _____

VISITE: _____

CT1_A

COÛTS

1. AU COURS DU DERNIER MOIS, avez-vous eu besoin de l'**AIDE** d'une autre personne pour les **ACTIVITÉS** suivantes à cause de votre problème au dos? (Encerclez tout ce qui s'applique)

   Si vous n'avez pas eu besoin d'aide, cochez ici _____ et passer à la question numéro 4

   A. Prendre une douche ou un bain
   B. Vous habiller
   C. Faire les travaux ménagers (passer la balayeuse, laver le linge, laver la vaisselle, etc)
   D. Préparer les repas
   E. Magasiner pour des produits de base (épicerie, etc.)
   F. Faire les travaux d'entretien autour de la maison (tondre le gazon, pelleter, jardiner, etc)
   G. Vous occuper des enfants

2. AU COURS DU DERNIER MOIS, **DE QUI** avez-vous **REÇU DE L'AIDE** pour une des activités énumérées à la question 1 ? (Encerclez tout ce qui s'applique). Pour chaque réponse que vous encerclez, veuillez compléter les renseignements demandés.

   NOTE : Inclure les personnes dont le principal travail est ménager ou ménagères (écrire **ménager** ou **ménagère** pour le type de travail)

	Combien d'heure(s)/ semaine vous ont-il aidé	**Est ce qu'il ont pris congé du travail pour vous aider**		**Quel est le type de travail de la personne qui vous a aidé**
A.Conjoint(e)	_____	Non	Oui	_____
B.Enfant(s)	_____	Non	Oui	_____
C.Frère(s)/Soeur(s)	_____	Non	Oui	_____
D.Autre(s) Parent(s)	_____	Non	Oui	_____
E.Ami(s) ou voisin(s)	_____	Non	Oui	_____
F.Bénévole(s)	_____	Non	Oui	_____
G.CLSC (soins à domicile)	_____	Non	Oui	_____

DATE : _____

NE : _____

3. Si vous avez eu besoin d'aide AU COURS DU DERNIER MOIS pour une des activités énumérées à la question 1, avez-vous **PAYÉ** pour recevoir de l'**AIDE**? (Encerclez votre réponse).

   0. Non
   1. Oui (Si oui, combien d'heure(s)? _____ À combien de l'heure? $_____

4. AU COURS DU DERNIER MOIS, est-ce qu'une autre personne à pris congé du travail pour vous accompagner à vos traitements, visites chez le docteur, ou pour des examens (prise de sang, radiographies, etc) à cause de votre problème au dos? (inclure aussi les personnes dont le principal travail est à la maison et écrivez **ménager** ou **ménagère** pour le type de travail)

   0. Non
   1. Oui (si oui, veuillez compléter les information ci-dessous)

Relation de la personne avec vous	**Nombre d'heures de congé du travail**	**Type de travail**
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

5. Est-ce que vous travaillez présentement?

   0. Non
   1. Oui Type de travail (soyez le plus spécifique possible):_____

      _____

DATE : _____

NE : _____

6. Quelles sont les conditions suivantes qui s'appliquent le mieux à vous DANS LE MOIS QUI A PRÉCÉDÉ L'APPARITION DE VOTRE PROBLÈME au dos. (Encerclez tout ce qui s'applique)

   A. Travail à temps plein _____ heures par semaine
   B. Travail à temps partiel _____ heures par semaine
   C. Travail à la maison (ménager/ménagère) _____ heures par semaine.
   D. Arrêt de travail temporaire à cause de mon problème au dos..
   E. Sans emploi.
   F. Invalide pour raison(s) médicale(s).
   G. Travail bénévole
   H. Retraité.
   I. Étudiant
   J. Autre (décrire): _____

      _____

7. Quelles sont les conditions suivantes qui s'appliquent le mieux à vous PRÉSENTEMENT.(Encerclez tout ce qui s'applique)

   A. Travail à temps plein _____ heures par semaine
   B. Travail à temps partiel _____ heures par semaine
   C. Travail à la maison (ménager/ménagère) _____ heures par semaine.
   D. Arrêt de travail temporaire à cause de mon problème au dos.
   E. Arrêt de travail temporaire pour raison autre que mon problème au dos.
   F. Sans emploi à cause de mon problème au dos.
   G. Sans emploi pour raison autre que mon problème au dos.
   H. Invalide à cause de mon problème au dos.
   I. Invalide pour d'autre(s) raison(s) médicale(s).
   J. Travail bénévole
   K. Retraité à cause de mon problème au dos.
   L. Retraité pour raison autre que mon problème au dos.
   M. Étudiant
   N. Autre (décrire): _____

      _____

DATE : _____

NE : _____

8. Si vous êtes présentement en arrêt de travail temporaire, sans emploi ou invalide, veuillez indiquez quand vous avez cessé de travailler.

Date: _____ / _____ / _____
jour mois année

Répondez à la question 9 si vous avez un emploi à temps partiel ou à temps plein à l'extérieur de la maison, sinon, cochez ici _____ , passez à la question 10.

9. Comment votre dos affecte t-il votre habilité de travailler à l'extérieur? (encerclez toutes les réponses qui s'appliquent à vous)

A. Je ne travaille actuellement pas à l'extérieur à cause de mon problème au dos.
B. J'accomplis toutes mes tâches au travail sans difficulté et sans restriction.
C. J'accomplis toutes mes tâches au travail mais avec difficulté à cause de mon problème au dos
D. Mon employeur m'a affecté à des tâches limitées
E. Si ce n'était pas de mon dos, je travaillerais _____ heure(s) par semaine

Répondez à la question 10 si vous travaillez à la maison (ménager/ménagère), sinon, cochez ici _____ passez à la question 11.

10. Comment votre dos affecte-il votre habilité de travailler à la maison? (encerclez toutes les réponses qui s'appliquent à vous)

A. Je suis incapable de faire mon travail à la maison à cause de mon problème au dos.
B. Je fais toutes mes taches de travail sans difficulté et sans restriction.
C. Je fais toutes mes taches de travail mais avec difficulté à cause de mon problème au dos.
D. Je dois limiter mes taches de travail à cause de mon problème au dos.
E. Si ce n'était pas de mon dos, je travaillerais _____ heure(s) par semaine à la maison.

DATE : _____

NE : _____

11. Si vous étiez sur le marché du travail AU COURS DU DERNIER MOIS, avez-vous manqué des heures ou des jours de travail à cause de votre problème au dos ou de vos traitements?
Si vous étiez sans emploi, cochez ici _____ et passer à la question 12.

    0. Non
    1. Oui
    Si oui, combien d'heure(s) ou de jour(s) avez-vous manqué? ____ heure(s)_____ jour(s)

12. Avez-vous reçu ou recevez vous présentement des **INDEMNITÉS DE LA CSST** pour votre problème au dos?

    0. Non
    1. Oui
    Si oui, indiquez les dates: _____ / _____ / _____ au _____ / _____ / _____
    jour mois année jour mois année

13. Combien de fois avez-vous eu les **TESTS** suivants AU COURS DU DERNIER MOIS (mois)? Encerclez le numéro approprié pour chaque test ou procédure (encerclez 0 si vous n'avez pas eu le test)

A. Radiographie du dos	0	1	2	3 ou plus
B. CT-Scan	0	1	2	3 ou plus
C. Résonnance Magnétique	0	1	2	3 ou plus
D. Scintigraphie osseuse	0	1	2	3 ou plus
E. Electromyogramme (EMG)	0	1	2	3 ou plus

Les question suivantes concernent les activités de loisirs (sports, passe-temps ou hobbies, activités sociales et activités en famille) que vous exécutez au cours d'une semaine typique.

14.a) Pratiquez-vous des activités sportives habituellement (jogging, golf, tennis, bicycle, quilles, baseball, natation, ski de fond, etc)?

    1. oui Passez à la question 14.b)
    0. non Est-ce à cause de votre problème de dos ? : 1. oui 0. non

    Si vous ne pratiquez pas d'activités sportives passez à la question 15

DATE : _____

NE : _____

14.b) AU COURS DU DERNIER MOIS, votre **PROBLÈME AU DOS** vous a t-il **LIMITÉ** dans vos **ACTIVITÉS SPORTIVES HABITUELLES** ?

1. Aucune limitation
2. Limitation légère
3. Limitation modérée
4. Limitation marquée
5. Impossible de faire mes activités sportives habituelles à cause de mon problème au dos

15. AU COURS DU DERNIER MOIS, votre **PROBLÈME AU DOS** vous a t-il **LIMITÉ** dans vos **PASSE-TEMPS HABITUELS** (lecture, cinéma, peinture, bingo, jouer au cartes, etc)?

1. Aucune limitation
2. Limitation légère
3. Limitation modérée
4. Limitation marquée
5. Impossible de faire mes passe-temps habituels à cause de mon problème au dos

16. AU COURS DU DERNIER MOIS, votre **PROBLÈME AU DOS** vous a t-il **LIMITÉ** dans vos **ACTIVITÉS SOCIALES HABITUELLES** (visiter un ami, parents, voisin, etc)?

1. Aucune limitation
2. Limitation légère
3. Limitation modérée
4. Limitation marquée
5. Impossible de faire mes activités sociales habituelles à cause de mon problème au dos

17. AU COURS DU DERNIER MOIS, votre **PROBLÈME AU DOS** vous a t-il **LIMITÉ** dans vos **ACTIVITÉS AVEC VOTRE FAMILLE** (jouer avec les enfants, sortie en famille, etc)?

1. Aucune limitation
2. Limitation légère
3. Limitation modérée
4. Limitation marquée
5. Impossible de faire mes activités familiales habituelles à cause de mon problème au dos

DATE : _____
NE : _____

CERTCS 1

PROTOCOLE D'INJECTION ÉPIDURALE CAUDALE

(Essai randomisé sur le traitement de la sténose spinale par épidurale)

1. Patient positionné en décubitus ventral.

2. Repérage anatomique de l'hiatus sacro-coccygien.

3. Rasage au besoin et désinfection à la Proviodine et alcool (si allergie à l'iode, Hibitane et alcool).

4. Anesthésie locale avec 2 à 5 cc de Xylocaïne 2% avec Épinéphrine.

5. Introduction d'un trocart (needle) N° 18 ou N° 20 dans l'hiatus sacro-coccygien, pour une distance de 1 à 6 cm.

6. Le médecin indique son degré de certitude sur le positionnement de l'aiguille dans le canal spinal. (Question posée par l'infirmière de recherche)

0	1	2	3	4	5	6	7	8	9	10

inadéquat adéquat

7. Le mandrin est retiré et il y a vérification d'absence d'écoulement sanguin ou de liquide céphalorachidien (LCR) après avoir demandé au patient de pratiquer une manoeuvre de Valsalva.

   - Si du sang s'écoule de l'aiguille, celle-ci est repositionnée.

   - Si du LCR s'écoule de l'aiguille, la procédure est cessée et un autre rendez-vous est donné au moins une semaine plus tard.

8. Une injection d'Omnipaque 300 (2 cc) avec l'utilisation d'un Medlon est pratiquée, et une vérification fluoroscopique est réalisée. Si le pattern d'injection est veineux, ou si le produit n'est pas dans le canal spinal, l'aiguille est repositionnée et le processus est repris à l'étape 7. (Données recueillies par l'infirmière de recherche)

Positionnement de l'aiguille:	essai 1	essai 2	essai 3
adéquat	☐	☐	☐
inadéquat	☐	☐	☐

DATE : _____
NE : _____

9. Le médecin procède à l'injection d'une solution d'un volume de 30 cc à une vitesse de 5cc/minute. **Ne pas divulguer à Mme Bujold la nature de l'injection.**

   a) 17 cc de salin 0.9% + 3 cc de méthylprednisolone (Dépomédrol: fioles uniques de 1 cc contenant 40 mg/cc de méthylprednisolone pour un total de 120 mg, et un préservatif, le myristyl-gamma-picolinium ne contenant pas d'alcool benzilique) + 10 cc d'Omnipaque 300.
   groupe traité

   b) 20 cc de salin 0.9% + 10 cc d'Omnipaque 300.
   groupe contrôle

10. Lorsque l'injection est terminée, le patient est positionné en décubitus latéral et un cliché est pratiqué après vérification fluoroscopique, de façon à bien identifier le degré de diffusion de la solution.

11. Le patient est gardé en décubitus latéral pour 10 à 15 minutes sur une civière à l'extérieur de la salle de fluoroscopie.

DATE : _____
NE : _____

QUESTIONNAIRE POST-INJECTION

(Les questions suivantes sont posées par l'assistante de recherche)

1. L'injection a t-elle provoqué des douleurs? (Encercler les réponses)

1 Oui
0 Non

Si oui : où étaient localisées ces douleurs?

0 région lombaire
1 fesses
2 menbre(s) inférieur(s) :_____ droit _____ gauche

2. Les douleurs provoquées étaient-elles similaires aux douleurs habituelles?

1 Oui
0 Non

3. Selon vous, quel produit a été injecté?

1 Stéroïdes
0 Placebo
2 Ne sait pas

Randomized Controlled Study on the Use of Epidural Steroid injections in Lumbar Spinal Stenosis

REGISTRATION

Center: 1 = HND 2 = IPQ

Date: _____-_____-_____
Year Month Day

Study ID#: _____

MRN: _____

SSN: _____

Name: _____

DOB: _____-_____-_____
Year Month Day

Address: _____

_____

Gender: 1 Male 0 Female

Telephone: (H) (_____) _____ - _____

Height: _____ cm

(W) (_____) _____ - _____

Weight: _____ kg

Race: 0 White 1 Black 2 Hispanic 3 Asian 4 Other

Inclusion Criteria (Eligibility = answers YES to the items A to D and NO to the items E to H)	Yes	No
A- Age > 45 years?	1	0
B- Pain or paresthesia in the back, buttock or legs typical of lumbar spinal stenosis (↗ by spine extension / walking, ↘ by spine flexion / sitting)	1	0
C- Radiographic confirmation of spinal canal narrowing	1	0
D- Able to complete questionnaires	1	0
E- The patient has a coagulopathy or is currently receiving an anti-coagulant therapy?	1	0
F- Received an epidural steroid injectionin the last 4 months	1	0
G- History of spinal inflammatory diseases	1	0
H- Allergy to local anesthetic (Xylocaine) or injectable steroids	1	0

Were the following tests performed?

1. Spine CT 0 No 1 Yes if yes, where_____, when_____
2. Spine MRI 0 No 1 Yes if yes, where_____, when_____

Referring Physician: _____ Lic. _____

Scheduled date for the first epidural: _____ - _____ - _____
Year Month Day

Refuse to participate: ☐

Randomized Controlled Study on the Use of Epidural Steroid injections in Lumbar Spinal Stenosis

PHYSICIAN

Date: _____-_____-_____ Yr. Mo. Day

Center: 1 = HND 2 = IPQ (please circle)

Study ID#: _____

MRN: _____

VISITE:_____

Spine Surgical History:

Has the patient had ONE or more PRIOR procedures?
(Please circle the correspondent level and if multiple surgery, indicate year of the last procedure)

1. **Laminectomy** 0 No
   1 Yes--> Level(s)? L2L3 L3L4 L4L5 L5S1 Other(s)____ year____
2. **Fusion** 0 No
   1 Yes--> Level(s)? L2L3 L3L4 L4L5 L5S1 Other(s)____ year____
3. **Discectomy** 0 No
   1 Yes--> Level(s)? L2L3 L3L4 L4L5 L5S1 Other(s)____ year____
4. **Other BACK surgery** 0 No
   1 Yes _____ year, _____
   _____
5. **How CONFIDENT are you about the CLINICAL DIAGNOSIS of lumbar spinal stenosis in this patient?**
   (please check the appropriate box)

0	1	2	3	4	5	6	7	8	9	10

0% confident 100% confident

6. **How CONFIDENT are you that this PATIENT will BENEFIT from ESI?**
   (please check the appropriate box)

0	1	2	3	4	5	6	7	8	9	10

0% confident 100% confident

7. **Does the patient have pseudoclaudication (weakness, paresthesia or pain after prolonged walking or standing, only released by sitting or spine flexion)?** 0 = no 1 = yes
8. **Duration patient has had back pain:** ____ (months)
9. **Duration patient has had claudication:** ____ (months)
10. **Duration of leg pain:** ____ (months)

PHYSICAL EXAMINATION

11. **STRAIGHT LEG RAISING TEST:** 1 = positive (if produced typical radicular pain below the knee, at less than 60 degree of elevation)

(Please circle) 0 = negative

REFLEXES: **Use the following codes:** 0 = no response
1 = markedly diminished
2 = diminished
3 = normal
4 = hyperactive
5 = clonus

RIGHT		LEFT
13. _____	**Knee**	16. _____
14. _____	**Ankle**	17. _____

STRENGTH: **Use the following codes:** 5 = no movement
4 = trace
3 = cannot oppose gravity
2 = opposes gravity
1 = weak
0 = normal

RIGHT		LEFT
18. _____	**Knee Extension**	22. _____
19. _____	**Foot Dorsi-flexion**	23. _____
20. _____	**First Toe Extension**	24. _____
21. _____	**Foot Plantar-flexion**	25. _____

PIN: **Use the following codes:** 0 = normal 1 = abnormal

RIGHT		LEFT
26. _____	**Above patella**	30. _____
27. _____	**Medial malleolus**	31. _____
28. _____	**First web space**	32. _____
29. _____	**Small toe**	33. _____

VIBRATION: **Use the following codes:** 3 = markedly diminished or absent
2 = moderately diminished
1 = slightly diminished
0 = normal

RIGHT		LEFT
34. _____	**Great toe**	37. _____
35. _____	**Medial malleolus**	38. _____
36. _____	**Tibial tuberosity**	39. _____

Observational Study on the Use of Epidural Steroid Injections

in Lumbar Spinal Stenosis

BAS_DATE

BASELINE

Date: _____-_____-_____
Day Mth. Year

ND: _____

NE: _____

READ THIS BEFORE ANSWERING the questionnaire.

Thank you for your participation in this survey. You will find below, a number of questions related to your problems, how they affect your life, and how you cope with them.

Although it is **VERY IMPORTANT** for us that you **ANSWER TO ALL QUESTIONS,** you may skip over any of these if you have personal reasons to do so.

If you are unsure about how to answer a question, please give the best answer you can and make a comment in the **margins**.

1. Imagine a scale from 0 to 10 representing your PAIN, with 0 representing no pain at all and 10 representing extreme pain. On this scale, how would you rate your PAIN over the LAST WEEK?
(write a number between 0 and 10)

0	1	2	3	4	5	6	7	8	9	10
None										Extreme

2. IN THE PAST MONTH, how has your pain affected you when you stand?
(Please circle the answer that fits you best)

    1. I can stand for hours, without pain
    2. I can stand for hours, but it causes pain
    3. I can stand no more than an hour because of pain
    4. I can stand no more than ten minutes because of pain
    5. I can barely stand at all because of pain

DATE : _____

NE : _____

3. WHICH BOTHERS YOU THE MOST, pain in your back and buttocks OR pain in your legs?
(please circle the answer that fits you best)

1. Back and buttock pain much more than leg pain.
2. Back and buttock pain a little bit more than leg pain
3. Back and buttock pain as much as leg pain
4. Leg pain a little bit more than back or buttock pain
5. Leg pain much more than back or buttock pain

PLEASE ANSWER EACH OF THE FOLLOWING QUESTIONS by circling the answer that fits you best.

4. Which of these income groups represents your (and your spouse's) gross income for the past year?
(circle the answer that describes you best)

1. Less than $14,999/year
2. $15,000 - $29,999/year
3. $30,000 - $49,999/year
4. More than $50,000/year
5. Don't know

5. How many years have you went to school?

_____ Years

6. Have you graduated from ?

	Yes	No
1. Primary	( )	( )
2. High school	( )	( )
3. College	( )	( )
4. University	( )	( )

7. What is your current living arrangement ?

1. Live alone
2. Live with spouse
3. Live with other family members or friends
4. Live in retirement or nursing home
5. Other (specify _____)

DATE : _____

NE : _____

8. Please circle all of the following assistive devices you have used IN THE LAST MONTH.

1. None
2. Cane/crutch
3. Walkerj
4. Wheelchair

HAVE YOU NOTICED that your pain is relieved by:
(Please circle one answer for each line)

	Never	Sometimes	Usually	Always
9. bending forward?	0	1	2	3
10. walking?	0	1	2	3
11. sitting?	0	1	2	3

12. PLEASE LIST ALL your **CURRENT MEDICATIONS** and **DOSAGES** including those medicines which you take only as needed.

Medication **How Often**

_____

_____

_____

_____

_____

DATE : _____

NE : _____

What EXPECTATIONS do you have for your epidural injection?
(Please circle one answer for each line)

As a result of my epidural injection, I expect...	Not likely	Slightly likely	Somewhat likely	Very likely	Extremely likely
13. Relief of back and/or buttock pain	1	2	3	4	5
14. Relief of legs pain	1	2	3	4	5
15. Relief of numbness and/or tingling	1	2	3	4	5
16. To have a better balance and teadiness on my feet	1	2	3	4	5
17. To be able to do more everyday household or yard activities	1	2	3	4	5
18. To be able to do more recreational activities such as sports or go for a long walk	1	2	3	4	5
19. To be able to sleep more comfortably	1	2	3	4	5

DATE : _____

NE : _____

How IMPORTANT are the following <u>treatment outcomes</u> for you?
(Please circle one answer for each line)

How important is...	Not important	Slightly important	Somewhat important	Very important	Extremely important
20. Relief of back and/or buttock pain	1	2	3	4	5
21. Relief of leg pain	1	2	3	4	5
22. Relief of numbness and/or tingling	1	2	3	4	5
23. To have a better balance and steadiness on my feet	1	2	3	4	5
24. To be able to do more everyday household or yard activities	1	2	3	4	5
25. To be able to do more recreational activities such as do sports or go for a long walk	1	2	3	4	5
26. To be able to sleep more comfortably	1	2	3	4	5

DATE : _____

NE : _____

The following questions ask about SERVICES, DOCTOR VISITS and other EXPERIENCES you have had in the LAST MONTHS. (Please CIRCLE one response for EACH QUESTION)

27. Did you ever receive an epidural injection in the past ?

0. No Go to question 28
1. Yes

If yes, was it for your low back broblem (spinal stenosis) ?

0. No Go to question 28
1. Yes

If yes, how many injections and when ? _____

_____

_____

28. In the LAST MONTH, how many DOCTOR VISITS have you had because of your back?

_____ visits

29. In the LAST MONTH, have you seen a VISITING NURSE because of your back problem?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)?

30. In the LAST MONTH, have you seen a PHYSICAL THERAPIST because of your back problem?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)?

DATE : _____

NE : _____

31. In the LAST MONTH, have you seen an OCCUPATIONAL THERAPIST because of your back problem?

    0. No
    1. Yes
    If yes, how many _____ visits a week, and for how many _____ week(s)?

32. In the LAST MONTH, have you seen an OSTEOPATH because of your back problem?

    0. No
    1. Yes
    If yes, how many _____ visits a week, and for how many _____ week(s)?

33. In the LAST MONTH, have you seen a CHIROPRACTOR because of your back problem?

    0. No
    1. Yes
    If yes, how many _____ visits a week, and for how many _____ week(s)?

34. In the LAST MONTH, Have you seen a MASSAGE THERAPIST because of your back problem?

    0. No
    1. Yes
    If yes, how many _____ visits a week, and for how many _____ week(s)?

35. In the LAST MONTH, have you seen a specialist in ACUPUNCTURE because of your back problem?

    0. No
    1. Yes
    If yes, how many _____ visits a week, and for how many _____ week(s)?

36 In the LAST MONTH, have you attended a BACK SCHOOL because of your back problem?

    0. No
    1. Yes
    If yes, how many _____ visits a week, and for how many _____ week(s)?

DATE : _____

NE : _____

37. In the LAST MONTH, have you had a CORSET for your back?

0. No
1. Yes

38. In the LAST MONTH, have you had TENS for your back?

0. No
1. Yes

39. DURING THE LAST MONTH, how many time(s) have you been hospitalized?

_____ Hospitalizations

Please indicate the reason(s) for each hospitalization, the name of the hospital and the number of days you have been hospitalized.

Name of hospital	Reason for admission	Number of days

2 B
M_1

Randomized Controlled Trial on the Use of Epidural Steroid injections in Lumbar Spinal Stenosis

1 - 2 - 3 - 6 - 12 MONTHS

Date: _____-_____-_____
Day Mth. Year

ND: _____

NE: _____

VISITE: _____

READ THIS BEFORE ANSWERING the questionnaire.

Thank you for your participation in this survey. You will find below, a number of questions related to your problems, how they affect your life, and how you cope with them.

Although it is **VERY IMPORTANT** for us that you **ANSWER TO ALL QUESTIONS,** you may skip over any of these if you have personal reasons to do so.

If you are unsure about how to answer a question, please give the best answer you can and make a comment in the **margins**.

1. Imagine a scale from 0 to 10 representing your PAIN,with 0 representing no pain at all and 10 representing extreme pain. On this scale, how would you rate your PAIN over the LAST WEEK? (Write a number between 0 and 10)

0	1	2	3	4	5	6	7	8	9	10

None Extreme

2. IN THE PAST MONTH, how has your pain affected you when you stand? (Please circle the answer that fits you best)

   1. I can stand for hours, without pain
   2. I can stand for hours, but it causes pain
   3. I can stand no more than an hour because of pain
   4. I can stand no more than ten minutes because of pain
   5. I can barely stand at all because of pain

Date: _____

NE: _____

3. WHICH BOTHERS YOU THE MOST, pain in your back and buttock OR pain in your legs? (Please circle the answer that fits you best)

   1. Back and buttock pain much more than leg pain.
   2. Back and buttock pain a little bit more than leg pain
   3. Back and buttock pain as much as leg pain
   4. Leg pain a little bit more than back or buttock pain
   5. Leg pain much more than back or buttock pain

HAVE YOU NOTICED that your pain is relieved by:
(Please circle one answer for each line)

	Never	Sometimes	Usually	Always
4. bending forward?	0	1	2	3
5. walking?	0	1	2	3
6. sitting?	0	1	2	3

7. Please circle all of the following assistive devices you have used IN THE LAST MONTH.

   1. None
   2. Cane/crutch
   3. Walker
   4. Wheelchair

Date: _____

NE: _____

8a. PLEASE LIST ALL your **current medications** and **dosages** including those medicines which you take only as needed.

Medication	**How often**

8b. # tylénol depuis la dernière visite:_____

9. HOW MANY INJECTIONS have you received in your spine since the beginning of the study? (please include the first injection and write the total number)

_____ epidural injections
_____ other type of spine injections

10. Did the injection(s) in your spine RELIEVE the PAIN?
(Please circle the answer that fits you best)

1. Yes, eliminated the pain entirely
2. Yes, eliminated almost all of the pain
3. Yes, eliminated some of the pain
4. No, did not eliminate the pain at all
5. No, now the pain is worse

Date: _____

NE: _____

NOW, we would like to find out how SATISFIED you are with your INJECTION.

11. Now that you have learned a lot about injections for spinal stenosis, if you could go back in time, would you choose to have the back injection?

    1. Yes, definitely
    2. Yes, probably
    3. No, probably not
    4. No, definitely not

The following questions are about SERVICES, TESTS, and VISITS TO THE DOCTOR you have had in the LAST MONTH
(Please CIRCLE one response for EACH QUESTION)

12. In the LAST MONTH, how many times did you GO TO THE DOCTOR because of your back?

    _____ visits

13. In the LAST MONTH, have you seen a VISITING NURSE because of your back problems?

    0. No
    1. Yes
       If yes, how many _____ visits a week, and for how many _____ week(s)

14. During the LAST MONTH, have you seen a PHYSICAL THERAPIST because of your back problems?

    0. No
    1. Yes
       If yes, how many _____ visits a week, and for how many _____ week(s)

Date: _____

NE: _____

15. During the LAST MONTH, have you seen an OCCUPATIONAL THERAPIST because of your back problems?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)

16. During the LAST MONTH, have you seen an OSTEOPATH because of your back problems?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)

17. During the LAST MONTH, have you seen a CHIROPRACTOR because of your back problems?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)

18. During the LAST MONTH, have you seen a MASSAGE THERAPIST because of your back problems?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)

19. During the LAST MONTH, have you seen a specialist in ACUPUNCTURE because of your back problems?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)

Date: _____

NE: _____

20. During the LAST MONTH, have you attended a BACK SCHOOL because of your back problems?

0. No
1. Yes
   If yes, how many _____ visits a week, and for how many _____ week(s)

21. During the LAST MONTH, have you had a CORSET for your back?

0. No
1. Yes

22. During the LAST MONTH, have you had TENS for your back?

0. No
1. Yes

23. DURING THE LAST MONTH, how many time(s) have you been hospitalized?

_____ Hospitalizations

Please indicate the reason(s) for each hospitalization, the name of the hospital and the number of days you have been hospitalized.

Name of hospital	Reason for admission	Number of days

Date:_____

NE: _____

VISITE: _____

SSP1

SYMPTOMS SEVERITY SCALE

1. IN THE LAST MONTH, how would you describe the pain you have had on average including pain in your back, buttocks and pain that goes down the legs?
   (Please circle one reply)

   0. None
   1. Mild
   2. Moderate
   3. Severe
   4. Very severe

2. IN THE LAST MONTH, how would you describe the pain in your back and buttocks?
   (Please circle one reply)

   0. None
   1. Mild
   2. Moderate
   3. Severe
   4. Very severe

3. IN THE LAST MONTH, how would you describe the pain in your legs or feet?
   (Please circle one reply)

   0. None
   1. Mild
   2. Moderate
   3. Severe
   4. Very severe

Date:_____

NE: _____

4. IN THE LAST MONTH, how would you describe the numbness or tingling in your legs or feet?
(Please circle one reply)

   0. None
   1. Mild
   2. Moderate
   3. Severe
   4. Very severe

5. IN THE LAST WEEK, how would you describe the weakness in your legs or feet?
(Please circle one reply)

   0. None
   1. Mild
   2. Moderate
   3. Severe
   4. Very severe

6. IN THE LAST MONTH, how often have you had back, buttock or leg pain?
(Please circle one reply)

   0. Never
   1. Less than once a week
   2. At least once a week
   3. Everyday, for at least a few minutes
   4. Everyday, for most of the day
   5. Every minute of the day

7. IN THE LAST MONTH, how would you describe the problems with your balance?
(Please circle the reply which describes you best)

   0. No, I have had no balance problem
   1. Yes, sometimes, I feel my balance is off, or that I am not sure-footed
   2. Yes, often, I feel my balance is off, or I am not sure-footed

Date:_____

NE: _____

WALKING CAPACITY SCALE

1. IN THE LAST MONTH, on a typical day, how far have you been able to walk?

    1) over two miles (3 km)
    1) over one mile (1.5 km) but less than two miles (3 km)
    3) over two blocks, but less than one mile (1.5 km)
    4) over fifty feet (15 meters) but less than two blocks
    5) less than fifty feet (15 meters)

2. IN THE LAST MONTH, have you:
   (Please circle one reply for each question)

	Yes, without problem	Yes, but with occasional problems	Yes, but often with pain	Yes, but always with pain	No, unable to do
A. taken walks outdoors or in malls for pleasure?	1	2	3	4	5
B. been shopping for groceries or other items?	1	2	3	4	5
C. walked around the different rooms in your house or apartment?	1	2	3	4	5
D. Walked from your bedroom to the bathroom?	1	2	3	4	5

Date:_____

NE: _____

SATISFACTION SCALE

1. NOW, we would like to know if you are SATISFIED with your injection

   HOW **SATISFIED** are you with:
   (Please circle one reply for each question)

	Very satisfied	Moderately satisfied	Moderately dissatisfied	Very dissatisfied
A. the overall results of the injection?	1	2	3	4
B. the relief of your numbness and tingling?	1	2	3	4
C. the relief of your pain?	1	2	3	4
D. your ability to walk comfortably?	1	2	3	4
E. your ability to do housework, yard work or your job?	1	2	3	4
F. your strength in the thighs, legs and feet?	1	2	3	4
G. your balance or steadiness on your feet?	1	2	3	4

Date: _____

NE: _____

VISITE: _____

QBP_1

QUEBEC

BACK PAIN

DISABILITY SCALE

Date: _____

NE: _____

This questionnaire is about the way your back pain is affecting your daily life. People with back problems may find it difficult to perform some of their daily activities. We would like to know if you find it difficult to perform any of the activities listed below, because of your back. For each activity there is a scale from 0 to 5. Please choose one response option for each activity (do not skip any activities), and circle the corresponding number.

Today, do you find it difficult to perform the following activities because of your back?

	Not difficult at all	Minimally difficult	Somewhat difficult	Fairly difficult	Very difficult	Unable to do
1. Get out of bed	0	1	2	3	4	5
2. Sleep through the night	0	1	2	3	4	5
3. Turn over in bed	0	1	2	3	4	5
4. Ride in a car	0	1	2	3	4	5
5. Stand up for 20-30 minutes	0	1	2	3	4	5
6. Sit in a chair for several hours	0	1	2	3	4	5
7. Climb one flight of stairs	0	1	2	3	4	5
8. Walk a few blocks (300 - 400 m)	0	1	2	3	4	5
9. Walk several miles	0	1	2	3	4	5
10. Reach up to high shelves	0	1	2	3	4	5

Date: _____

NE: _____

Today, do you find it difficult to perform the following activities <u>because of your back?</u>

	Not difficult at all	Minimally difficult	Somewhat difficult	Fairly difficult	Very difficult	Unable to do
11. Throw a ball	0	1	2	3	4	5
12. Run one block (about 100 m)	0	1	2	3	4	5
13. Take food out of the fridge	0	1	2	3	4	5
14. Make your bed	0	1	2	3	4	5
15. Put on socks (pantyhose)	0	1	2	3	4	5
16. Bend over to clean the bathtub	0	1	2	3	4	5
17. Move a chair	0	1	2	3	4	5
18. Pull or push heavy doors	0	1	2	3	4	5
19. Carry 2 bags of groceries	0	1	2	3	4	5
20. Lift and carry a heavy suitcase	0	1	2	3	4	5

DATE : _____
NE : _____
VISITE : ____ SF1

MOS Short form 36 (SF-36)

The following questions are about your health, and your personal behaviors.

Answer each question by circling the appropriate number(s) or filling in the blank as directed.

If you are unsure about how to answer a question, please give the best answer you can and make a comment in the left margin.

1. In general, would you say your health is excellent, very good, good, fair or poor?

Excellent 1
Very good 2
Good 3
Fair 4
Poor 5

2. Compared to 12 months ago, how would you rate your health in general now?

Much better 1
Somewhat better 2
About the same 3
Somewhat worse 4
Much worse 5

DATE : _____
NE : _____

Health and Daily Activities

3. **The following questions are about activities you might do during a typical day. I'm going to ask if your health limits you in these activities a lot, a little or not at all. Please tell me which response describes you best.**

	Yes limited a lot	Yes limited a little	No, not limited at all
a. Does your health limit you in vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Does your heaith limit you in moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Does your health limit you in bending, kneeling, or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several blocks	1	2	3
i. Walking one block	1	2	3
j. bathing and dressing yourself	1	2	3

DATE : _____
NE : _____

4. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health? Please answer YES or NO for each question.**

	YES	NO
a. As a result of your physical health have you cut down on the amount of time you spent on work or other activities	1	2
b. Have you accomplished less than you would like	1	2
c. Have you been limited in the kind of work or other activities	1	2
d. Have you had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? Please answer YES or NO for each question.**

	YES	NO
a. As a result of any emotional problems have you cut down on the amount of time you spent on work or other activities	1	2
b. Have you accomplished less than you would like	1	2
c. Have you felt you didn't do work or other activities as carefully as usual	1	2

DATE : _____
NE : _____

6. **During the <u>past 4 weeks</u>, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all 1
Slightly 2
Moderately 3
Quite a bit 4
Extremely 5

7. **During the <u>past 4 weeks</u> how much <u>bodily</u> pain have you had on average?**

None 1
Very mild. 2
Mild 3
Moderate 4
Severe 5
Very severe 6

8. **During <u>the past 4 weeks</u>, how much did pain interfere with your normal work (including work both outside the home and housework)?**

Not at all 1
Slightly 2
Moderately 3
Quite a bit 4
Extremely 5

DATE : _____
NE : _____

9. **These questions are about how you feel and how things have been with you <u>during the past month</u>. For each question, please indicate the answer that comes closest to the way you have been feeling, for example "all of the time, most of the time, a good bit of the time, some of the time, a little of the time, none of the time".**

How much of the time during the <u>past month</u>...
(Please circle only one number per line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person	1	2	3	4	5	6
c. Have you felt so down in the dumps nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

DATE : _____
NE : _____

10. **During the PAST 4 WEEKS, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc)?**

All of the time 1
Most of the time 2
Some of the time 3
A Little of the time 4
None of the time 5

11. **The next statements are about your health in general. Please say if you think they are "definitely true, mostly true, you are not sure, mostly false or definitely false".**

	Definitely true	Mostly true	Not sure	Mostly false	Definitively false
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

DATE : _____

NE : _____

VISITE: ____ *HUI_1*

MODIFIED HUIIII/ENGLISH VERSION

The following questions ask about your ability to do certain activities. Answer every question by circling the number that corresponds best to your ability to perform the activity. There is no right or wrong answer to the questions. If you are unsure about how to answer a question, please give the best answer you can and make a comment under the question.

1. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to **SEE** well enough to **READ ORDINARY NEWSPRINT**? (circle one)

   1. Able to see well enough **without** glasses or contact lenses.
   2. Able to see well enough **with** glasses or contact lenses.
   3. Unable to see well enough even with glasses or contact lenses.
   4. Unable to see at all.

2. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to **SEE** well enough to **RECOGNIZE A FRIEND** on the **OTHER SIDE OF THE STREET**? (circle one)

   1. Able to see well enough **without** glasses or contact lenses.
   2. Able to see well enough **with** glasses or contact lenses.
   3. Unable to see well enough even with glasses or contact lenses.
   4. Unable to see at all.

DATE : _____

NE : _____

3. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to **HEAR** what is **SAID IN A GROUP CONVERSATION** with at least **THREE OTHER PEOPLE**? (circle one)

   1. Able to hear what is said **without** a hearing aid.
   2. Able to hear what is said **with** a hearing aid.
   3. Unable to hear what is said even with a hearing aid.
   4. Unable to hear what is said, but don't wear a hearing aid.
   5. Unable to hear at all.

4. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to **HEAR** what is **SAID IN CONVERSATION WITH ONE OTHER PERSON** in a **QUIET** room? (circle one)

   1. Able to hear what is said **without** a hearing aid.
   2. Able to hear what is said **with** a hearing aid.
   3. Unable to hear what is said even with a hearing aid.
   4. Unable to hear what is said, but don't wear a hearing aid.
   5. Unable to hear at all.

5. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to be **UNDERSTOOD** when **SPEAKING** the same language with **STRANGERS**?(circle one)

   1. Able to be understood **completely**.
   2. Able to be understood **partially**.
   3. Unable to be understood
   4. Unable to speak at all.

DATE : _____

NE : _____

6. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to be **UNDERSTOOD** when speaking with **PEOPLE WHO KNOW YOU WELL**? (circle one)

   1. Able to be understood **completely**.
   2. Able to be understood **partially**.
   3. Unable to be understood
   4. Unable to speak at all.

7. DURING THE PAST FOUR WEEKS, which of the following statements best describes **HOW YOU FEEL**? (circle one)

   1. Happy and interested in life
   2. Somewhat happy
   3. Somewhat unhappy
   4. Very unhappy
   5. So unhappy that life is not worthwhile

8. DURING THE PAST FOUR WEEKS, which of the following statements best describe your **INTENSITY OF PAIN AND DISCOMFORT**? (circle one)

   1. Free of pain and discomfort.
   2. Mild to moderate pain or discomfort that prevents no activities.
   3. Moderate pain or discomfort that prevents a few activities.
   4. Moderate to severe pain or discomfort that prevents some activities.
   5. Severe pain or discomfort that prevents most activities.

DATE : _____

NE : _____

9. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to **REMEMBER THINGS**? (circle one)

   1. Able to remember most things.
   2. Somewhat forgetful.
   3. Very forgetful.
   4. Unable to remember anything at all.

10. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY** to **THINK** and **SOLVE DAY TO DAY PROBLEMS**? (circle one)

   1. Able to think clearly and solve day to day problems.
   2. Have a little difficulty when trying to think and solve day to day problems.
   4. Have some difficulty when trying to think and solve day to day problems.
   5. Have great difficulty when trying to think and solve day to day problems
   6. Unable to think or solve day to day problems.

11. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY TO WALK AND RUN**? (circle one)

   1. Able to walk and run without limitation.
   2. Able to walk without limitation but limited when running.
   3. Able to walk no more than one mile and unable to run.
   4. Able to walk no more than several blocks.
   5. Able to walk no more than 1 block.
   6. Can only walk around the house.
   7. Cannot walk at all.

DATE : _____

NE : _____

12. DURING THE PAST FOUR WEEKS, which of the following statements best describes your **ABILITY TO USE YOUR UPPER EXTREMITIES**?

Note: By UPPER EXTREMITIES we mean your shoulders, arms, hands, and fingers.

Note: SPECIAL TOOLS refers to hooks for buttoning clothes, gripping devices for opening jars or lifting small items, long handle utensil for eating, reacher to get objects on high shelf, and other devices to compensate for limitations of shoulders, arms, hands and fingers.

1. Full use of your upper extremities without limitation.

2. Able to do moderate activities without limitation with your upper extremities such as raking leaves, vacuuming, carrying shopping bags or typing continuously for one hour, but limited in more vigorous activities.

3. Able to do light activities without limitation with your upper extremities such as bathing or dressing, but limited in moderate activities.

4. Difficulty doing light activities with your upper extremities such as bathing or dressing but do not require the use of special tools or the help of another person.

5. Require the use of special tools to do light activities with your upper extremities such as bathing or dressing but do not require the help of another person.

6. Require the help of another person for all tasks with your upper extremities (not independent even with use of special tools).

Date:_____
SN:_____
VISITE: _____

CT1_A

QUESTIONNAIRE ON COSTS

1. DURING THE LAST 4 WEEKS, have you, because of your back problem, required **HELP** from another person for the following **ACTIVITIES**? (Please circle each item which applies)

   If you did not require any help, please check here_____ and go on to question No. 4.

   A. Take a shower or a bath
   B. Get dressed
   C. Do the domestic chores (vacuum, wash clothes, make the bed, etc.)
   D. Prepare the meals
   E. Shop for basic items (groceries, etc.)
   F. Do work around the house (mow the grass, shovel, garden, etc.)
   G. Take care of the children

2. If you have required help DURING THE LAST 4 WEEKS for one of the activities mentioned in question 1, who helped you? (circle each item which applies)

   For each answer that you circle, please supply the required information.

   NOTE: Include the persons whose principal work is housework (write **homemaker** as the type of work)

	How many hour(s)/ week(s) did they help you	**Did they absent themselves from work to help you**	**What is the type of work of the person who helped you**
A. Spouse	_____	No Yes	_____
B. Child(ren)	_____	No Yes	_____
C. Brother(s) Sister(s)	_____	No Yes	_____
D. Other Relative(s)	_____	No Yes	_____
E. Friend(s) Neighbour(s)	_____	No Yes	_____
F. Voluntary helper	_____	No Yes	_____
G. CLSC (home care)	_____	No Yes	_____

3. If you have required help DURING THE LAST 4 WEEKS for one of the activities mentioned in question 1, did you have to **pay** to receive help? (Circle your answer)

   0. No
   1. Yes If yes, how many hour(s)? _____ How much per hour? $_____

4. DURING THE LAST 4 WEEKS, has another person absented himself(herself) from work to accompany you to your treatments, to visit the doctor, or to have medical tests (blood test, X-Rays, etc.) because of your back problem? (please include those persons who do housework and write **homemaker** as their type of work).

   0. No
   1. Yes (if yes, please supply the information below)

Person's relationship to you	**Number of hours of absence from work**	**Type of work**
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

5. Are you working presently?

   0. No
   1. Yes Type of work (be as specific as possible): _____
      _____

Date:_____
SN:_____

6. Which of the following conditions best applied to you in the MONTH PRECEDING THE BEGINNING OF YOUR BACK PROBLEM. (Please circle each item that applies to you)

A. Full-time work _____ hours per week.
B. Part-time work _____ hours per week.
C. Housework _____ hours per week.
D. Tempporary sick leave
E. Unemployed.
F. Disabled for medical reason(s).
G. Voluntary work.
H. Retired.
I. Student.
J. Other (specify): _____

7. At this time, which of the following conditions best applied to you ? (Please circle each item that applies to you)

A. Full-time work _____ hours per week.
B. Part-time work _____ hours per week.
C. Housework _____ hours per week.
D. Temporary sick leave due to my back problem.
E. Temporary sick leave for a reason other than my back problem.
F. Unemployed due to my back problem.
G. Unemployed due to a reason other than my back problem.
H. Disabled due to my back problem.
I. Disabled for other medical reason(s).
J. Voluntary work.
K. Retired due to my back problem.
L. Retired for a reason other than my back problem.
M. Student
N. Other (describe): _____

_____

Date:_____
SN:_____

8. If you are presently on temporary sick leave, unemployed or disabled, please indicate when you stopped working.

   Date: _____ / _____ / _____
   day month year

Please answer question 9 if you are EMPLOYED OUTSIDE YOUR HOME.
If you are not employed outside your home, check here _____ and go on to question 10.

9. How does your back affect your capacity to work outside your home? (please circle all answers which apply to you)

   A. I am not working outside presently due to my back problem.
   B. I execute all my tasks at work without difficulty and with no restriction.
   C. I execute all my tasks at work but with difficulty because of my back problem.
   D. My employer has assigned me to restricted duties.
   E. It not for my back, I would be working _____ hour(s) a week.

Answer question 10 if you WORK IN YOUR HOME (housework).
If you are not doing housework, please check here _____ and go on to question 11.

10. How does your back affect your capacity to do housework? (please circle all answers which apply to you).

   A. I am incapable of doing my housework due to my back problem.
   B. I do all my housework without any difficulty and with no restriction.
   C. I do all my housework , but with difficulty due to my back problem.
   D. I must limit my housework due to my back problem.
   E. If not for my back, I would spend _____ hour(s) a week doing housework.

Date:_____
SN:_____

11. If you were EMPLOYED during the LAST 4 WEEKS, did you miss hours or days of work because of your back problem or for treatments?
If you were unemployed, check here ____ and go on to question 12.

0. No
1. Yes

If yes, how many hour(s) or day(s) did you miss? _____ hour(s) _____ day(s)

12. Have you received or are you presently receiving an indemnity from the CSST for your back problem?

0. No
1. Yes If yes, indicates the dates: _____ / _____ / _____ to _____ / _____ / _____
day month year day month year

13. How many times have you been subjected to the following tests for your back during the last 4 weeks? Please circle the appropriate number for each test or procedure (circle 0 if your did not undergo any test)

A. X-Ray	0	1	2	3 or more
B. CT-Scan	0	1	2	3 or more
C. Magnetic Resonance Imaging (MRI)	0	1	2	3 or more
D. Bone scan	0	1	2	3 or more
E. Nerve conduction test (EMG)	0	1	2	3 or more

The following questions cover LEISURE ACTIVITIES (sports, hobbies, social activities and family activities) in which you participate during a typical week.

14.a) Do you usually practice sporting activities ? (jogging, golf, tennis, bicycling, bowling, baseball, natation, cross-contry skying,etc)

1. Yes Go to question 14.b)
0. No If no, is it becauses of your back problem ? 0. No 1. Yes

If you do not practice sporting activities, go to question 15.

Date:_____
SN:_____

14.b) DURING THE LAST 4 WEEKS, has your back problem limited your usual sporting activities ?

1. No limitation
2. Slight limitation
3. Moderate limitation
4. Severe limitation
5. Impossible to engage in my usual sporting activities due to my back problem.

15. DURING THE LAST 4 WEEKS, has your back problem limited your usual hobbies (cinema, painting, bingo, cards, etc.)?

1. No limitation
2. Slight limitation
3. Moderate limitation
4. Severe limitation
5. Impossible to devote myself to my usual hobbies due to my back problem.

16. DURING THE LAST 4 WEEKS, did your back problem limit your usual social activities (visit friends, relatives, neighbours, etc.)?

1. No limitation
2. Slight limitation
3. Moderate limitation
4. Severe limitation
5. Impossible to engage in my usual social activities due to my back problem.

17. DURING THE LAST 4 WEEKS, has your back problem limited your family activities (play with the children, family outing, etc.)?

1. No limitation
2. Slight limitation
3. Moderate limitation
4. Severe limitation
5. Impossible carry on with my usual family activities due to my back problem.

DATE : _____
NE : _____

PROTOCOL OF CAUDAL EPIDURAL INJECTION IN THE SACRO-COCCYGIAN HIATUS

(Randomized trial on the treatment of spinal stenosis by epidural injections)

1. Patient positioned in a prone position.

2. Anatomical location of the sacro-coccygian hiatus.

3. Shaving of the area if needed and disinfection with Proviodine and alcohol (if allergic to iodine, use of Hibitane and alcohol).

4. Local anaesthetic with 2 to 5 cc of Xylocaïne 2% with Epinephrin.

5. Insertion of a No 18 or No 20 trocar in the sacro-coccygian hiatus to a depth of 1 to 6 cm.

6. The physician indicates to which degree he is certain that the needle has been adequately inserted (or positioned) in the spinal canal. (Please circle one answer only).

0	1	2	3	4	5	6	7	8	9	10

Inadequate adequate

7. The trocar is removed and verification is made that there is no oozing of blood or of cerebro-spinal fluid (CSF) by asking the patient to execute a Valsalva manoeuvre.

   - If blood oozes out, the needle is repositioned.

   - If CSF oozes out, the procedure is aborted and another appointment is fixed to at least a week later.

8. 2 cc of Omnipaque is injected with a Medlon and a fluoroscopic verification is made. If the injection pattern is venous, or if the solution is not in the spinal canal, the needle is repositioned and the procedure is repeated from step 7. (Data collected by the research assistant)

   Needle positioning : A spot film is taken and the research assistant shows it to the radiologist who assesses if positioning of the needle is correct or not.

	attempt 1	attempt 2	attempt 3
accurate	☐	☐	☐
Inaccurate	☐	☐	☐

DATE : _____
NE : _____

9. The physician injects 30 cc of solution at 5 cc/minute. **The research assistant remains blinded to the type of injection**.

   a) 17 cc of saline solution 0.9%+3 cc of methylprednisolone (Depomedrol: 1 cc vial containing 40 mg/cc of méthylprednisolone for a total of 120 mg, and a preservative, myristyl-gamma-picolinium without benzilic alcohol) + 10 cc of Omnipaque 300.
   Treated group

   b) 20 cc of saline 0.9% + 10 cc of Omnipaque 300.
   Control group

10. When the injection has been completed, the patient is placed in a lateral position ; after fluoroscopic verification, an X-Ray is taken in order to clearly identify the level of diffusion of the solution in the spinal canal.

11. The patient is kept on a wheeled stretcher outside the fluoroscopy room in a lateral position for 10 to 15 minutes.

DATE : _____
NE : _____

POST-INJECTION QUESTIONNAIRE

(Data collected by the research assistant)

1. Has the injection induced pain?

   1 yes
   0 no

   If yes : where was the pain?
   0 lumbar region
   1 buttocks
   2 lower limb(s) :_____ Right _____ Left

2. Was the induced pain similar to the usual pain?

   1 yes
   0 no

3. In your opinion, what product has been injected?

   1 steroïds
   0 Placebo
   2 Does not know