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Injection Treatment for Lower Back Pain in Older Adults with Lumbar Spinal Stenosis: A Dissertation

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INJECTION TREATMENT FOR LOWER BACK PAIN IN OLDER ADULTS WITH LUMBAR SPINAL STENOSIS

By

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INJECTION TREATMENT FOR LOWER BACK PAIN IN OLDER ADULTS WITH LUMBAR SPINAL STENOSIS

A Dissertation Presented

By

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DEDICATION

I would like to dedicate this dissertation to my late father, Robert Briggs, who passed away the same month I started this program in 2005. Without ever saying much, he inspired me to learn, to work hard, to accomplish and to better myself while I am on this earth. He also taught me to be self-sufficient and to always do my best, but to take time to enjoy the simple things in life. His appreciation for family, pets, dancing and music, influenced me to always make time for the pleasures many of us often take for granted. He will always be in my heart and an important figure in my life, and I thank him.

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ABSTRACT

Background: Lower back pain is one of the most common health-related complaints in the adult population. Thirty percent of Americans 65 years and older reported symptoms of lower back pain in 2004 [1]. With an aging population, the proportion of people over the age of 65 is expected to reach 20% by the year 2030. Because of this increase in older adults, lumbar spinal stenosis (LSS) associated with arthritic changes will also likely increase. In older adults, lower back pain is most often caused by degenerative lumbar spinal stenosis. Stenosis is the narrowing of the spinal canal, causing pressure on the nerve roots and is frequently treated surgically. Lumbar spinal stenosis is one of the most common reasons for back surgery in patients 65 years and older [2]. However, risks associated with surgery increase with age [3-5] and older patients may choose non-surgical treatment for their lower back pain, including injection treatment.

Injection treatment, usually consisting of anti-inflammatory medications and analgesics, has improved since the mid-1990's when fluoroscopic guidance was developed [6]. Information about injection treatment for lower back pain is limited, especially in the older population. An extensive review of published literature regarding injection treatment revealed a paucity of information about older adults diagnosed with lumbar spinal stenosis [6-13]. In this study, three aims were designed to gain more information about the effectiveness of injection treatment in older patients with lumbar spinal stenosis. In the first (retrospective) study, information about receipt of second

injections and time between injections was collected to examine injection usage. In the second and third (prospective) studies, information about pain relief and functional return following injection treatment was collected to examine the effectiveness of injection treatment in patients age 60 and older diagnosed with lumbar spinal stenosis. To our knowledge, such results have not been reported for this population in the literature.

Objective: Injection treatment is a commonly used non-surgical procedure to alleviate lower back pain in older adults. However, older patients do not have enough information about how long pain relief will last after treatment or the amount of pain relief and functional return they will experience. These studies focused on three topics: 1) usage of injection treatment; 2) effectiveness of injection treatment on pain relief; 3) effectiveness of injection treatment on functional return. In addition, the variations of the effectiveness were examined by selected patient attributes.

Methods: In a retrospective study, medical records of patients aged 60 years or older from a high volume dedicated spine center at the University of Massachusetts Memorial Hospital were retrospectively reviewed. This study included those diagnosed with degenerative LSS, who had not received an injection for lower back pain within six months, and whom were treated between June 1, 2006 and May 31, 2007.

In two prospective studies, patients scheduled for lumbar injection treatment between January 1 and June 30, 2008 were selected from the University of Massachusetts Memorial Hospital Spine Center. Selection criteria included patients age 60 and over, diagnosed with degenerative lumbar spinal stenosis and no previous lumbar injection within 6 months or lumbar surgery within 2 years. The Pain sub-score of the SF-36

questionnaire was used to measure pain at baseline and at one and three months post injection. The Physical Component Score (PCS) of the SF-36 questionnaire and the Oswestry Disability Index (ODI) were used to measure function at baseline and at one and three months post injection. Variations in longitudinal changes in scores by patient characteristics were analyzed in both unadjusted (univariate) analyses using one-way analysis of variance (ANOVA), and adjusted (multiple regression) analyses using linear mixed effects models.

Results: In the retrospective cohort, the mean age of the cohort was 68, 64% were female, 59% were married, with a mean Body Mass index of 32 kg/m2. Of 92 eligible patients, 57% returned for a second injection within six months of the first. The mean number of months between injections was 4.8 for all patients, ranging from 1 to 22 months. When patient characteristics were examined, the only variable that showed a statistically significant difference was age. Patients aged 70 years and older were found to be 67% less likely to return for a second injection when compared to patients age 60-69 (OR=0.33 (0.12 – 0.94)$p<.05$)). When age was examined as a continuous variable, the odds of having a second injection decreased by 10% for every year aged after age 60 (OR=0.90 (0.83 – 0.99);$p<.05$)).

In the prospective cohort, information was collected on 62 patients. Mean Pain scores improved significantly from baseline to one month (14.1 points), and from baseline to three months (8.3 points). Post injection changes in Pain scores varied by Body Mass Index (BMI) and baseline emotional health. Based on a linear mixed effects model analysis, higher baseline emotional health, as measured by the SF-36 Mental

Component Score (MCS≥50), was associated with greater reduction in pain over three months when compared to lower emotional health (MCS<50). In patients with higher emotional health, Pain scores improved by 14.1 ($p<.05$: 95%CI 6.9, 21.3). Mean function scores for both the PCS and ODI also improved significantly from baseline to one month (≥ 3 points), but not at three months. Post injection changes in PCS and ODI varied by age, Body Mass Index (BMI), co-morbidities and emotional status. Based on a linear mixed effects model analysis, higher baseline emotional health, as measured by the SF-36 Mental Component Score (MCS≥50), was associated with greater improvement of function at one and three months when compared to lower emotional health (MCS<50). In patients with higher emotional health, ODI improved by 17.8 points ($p<.0001$) over three months, and PCS improved by 6.1 points at one month and 4.6 points at three months.

Conclusion: Patients over age 70 do not return for repeat injection as frequently as patients age 60-69. In addition, each year a patient ages over age 60, they are 10% less likely to return for a repeat injection. Lower back pain in older adults with LSS is clinically significantly alleviated after injection treatment. In addition, injection treatment for LSS is associated with return of lost function needed for daily living activities in older adults. Pain relief and functional return varies by patient personal and clinical characteristics. Higher emotional health was associated with more pain relief and more functional return experienced over three months following injection treatment. Additional information is needed about why older patients do not return for second

injections at the same rate as younger patients and how emotional health affects response to injection treatment in older adults.

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CHAPTER 1

Outcomes of injection therapy treatment on lumbar spinal stenosis in older adults: A systematic review of the literature

INTRODUCTION

Lumbar stenosis is a condition that causes pain of the lower extremities and/or back when nerve roots are compressed by narrowing of the lumbar spinal canal. Lumbar stenosis occurs more frequently in aging adults [14]and affects five of every 1,000 Americans over age 50 [15]. Historically, laminectomy has been the surgical treatment of choice for lumbar stenosis in adults [16]. Laminectomy decompresses nerves near the spinal column thus alleviating pain and may return some lost functions. However, laminectomy procedures have been shown to have up to a 64% failure rate, defined as local tissue trauma and postoperative spinal instability [16]. Older adults have a greater risk of complications following surgery than younger patients including dementia [3], infection [4] and respiratory, cardiac and urinary tract complications [5]. Due to the high failure rate of this procedure, many physicians and patients choose non-surgical methods for treatment [17]. An emerging treatment to alleviate symptoms for lumbar stenosis is to inject steroids and analgesics. Although this procedure initially had many complications including spinal cord injury, myelopathy and spinal hematoma, procedure techniques have improved and many patients have experienced satisfying and long-lasting relief from lower back pain [6]. In addition, the development of fluoroscopic guidance has enabled physicians to deliver injected medications more accurately, causing fewer complications

[6]. However, there is little evidence available to predict outcomes from the procedure within older adults age 65 and older.

The purpose of this systematic review is to summarize the major findings in the current literature about pain, function, co-morbidities and complications following injection therapy used to treat lumbar stenosis in adults with a focus on older patients. This systematic review will summarize outcomes for people diagnosed with lumbar stenosis and receiving injection therapy. With the information presented in this review, primary care physicians may be able to provide more effective treatment and referrals for their older patients.

METHODS

SEARCH STRATEGY:

Literature search

Current literature published on this topic, were queried in MEDLINE and The Cochrane Review. The search terms "injection lumbar stenosis", "nonsurgical lumbar stenosis" and "conservative lumbar stenosis" were used to identify peer-reviewed articles published between 1996 (when fluoroscopic was developed and used in clinical practice) and 2006. Additional studies were identified using references from these studies.

Validity Assessment

All studies identified in the search were reviewed to determine if they met inclusion criteria and described below. Final assessment was made for both inclusion and exclusion criteria upon review of data available in each study. References were also

reviewed for potential studies addressing the research question. After review of all the included studies, data were abstracted and entered in a table.

Inclusion criteria:

To be reviewed, studies had to meet these criteria: 1) be in English, 2) published between October 1, 1996 and October 1, 2006, 3) subjects were adults diagnosed with lumbar stenosis and treated with injection therapy, and 4) outcomes measured were pain, function, comorbidities and perioperative complications. Since fluoroscopic guidance was used to more accurately deliver spinal injections in the mid-1990's, study inclusion was limited to studies published after 1995.

Exclusion criteria: Studies were excluded from the review if they 1) were case studies, 2) included subjects that had previous back surgery, 3) included subjects that had disc conditions, or 4) included subjects that were receiving other therapy (physical therapy, medications) combined with injection therapy. Studies evaluating multiple treatments would not allow attribution of outcomes to injections.

Analysis

Data extracted from the included studies were entered in a table that included author, year of publication, number of participants, mean age, effect/results, and whether or not information was collected on pain, function and complications for both people over and under age 65. Following identification of these studies, information was extracted on study design, sample size and age of participants. The key information extracted from the studies included outcome data from injection treatment, especially in patients over age 65.

RESULTS

The initial search identified 35 articles (Figure 1). Twenty-three study abstracts were excluded for the following reasons: six included patients with disc conditions, five were reviews, four were letters to the editor, three evaluated non-surgical treatment only (but not specifically injections), two combined injections with other treatments, two were published in a foreign language and one was a case study.

Twelve studies were then reviewed and five were excluded based on the following criteria: two included patients with disc conditions, two did not specify lumbar stenosis and one combined injections with other treatments. Seven studies were identified as meeting selection criteria and are listed in Table 1. Results extracted from each study are included in Table 2.

Diagnosis of Lumbar Stenosis

In the reviewed studies, lumbar stenosis was defined using a variety of criteria including: history of any leg and lower back pain, failed conservative management of pain symptoms and radiographic evidence showing narrowing of the spinal canal. Of the seven studies included, four specified confirmation of lumbar stenosis by magnetic resonance imaging and one required "radiographic evidence" of lumbar stenosis. Conditions identified as being associated with lumbar stenosis ranged from spondylolisthesis to spinal canal narrowing to nerve root compression. In addition, no patients had known lumbar disc disease. In four of the seven studies, pain was specified as one of the most useful diagnostic factors for lumbar stenosis. This ranged from lower back pain to radicular pain. In three of these four studies, patients' symptoms could not

be resolved by conservative treatment in order to be included in the study sample. In two of the four studies, pain relief from spinal flexion was also used as inclusion criteria.

Age

Information on the ages of patients was not consistently reported in the seven reviewed studies. In five of the seven studies, age ranges were reported and included patients ranging from age 17 to 92. Age means ranged between 54 and 77 years. None of the seven studies included information specifically on patients over age 65.

Follow-up

Follow-up periods varied greatly in the seven studies included in this review. Following baseline assessment and injection treatment for lumbar stenosis, the follow-up periods ranged from one week to 24 months. In three of the seven studies, only one follow-up period was used. In one of the studies, two follow-up periods were used and in three of the studies, three or more follow-up periods were used. In two of the seven studies, follow-up assessment did not begin until at least one month after the injection was given.

Measures:

A wide variety of instruments were used to assess pain and function in all seven studies. The list of pain instruments included: Visual Analog Scale [6, 9-11], Verbal Numeric Pain Scale [7] and the Stucki Questionnaire [8]. The list of function measures includes the Roland-Morris Disability Questionnaire [7], the Stucki Questionnaire [8], the Oswestry Disability Index [10] and walking or standing tolerance tests [6, 12]. Neither pain

nor function measures were consistent throughout the included study designs. Function measurements were particularly varied.

Pain

Pain relief was quantified in six of the seven studies and all reported relief following treatment by injection. No studies reported information specific to patients over age 65. Six studies identified examined the results of epidural steroid injection on pain, and all studies showed an improvement following treatment in people of all ages. Pain measures varied across studies and the pain scale most often used was the Visual Analog Scale, reported in four studies [6, 9-11]. These studies reported a reduction in pain, with the most notable result reported in Botwin's study showing at least a 50% reduction in pain in 75% of patients. A similar result was found in Barre's study, which showed at least a 50% reduction in pain, but only in 35% of patients. Two of the studies focused their reports of pain relief at several follow-up periods. The first study reported "continuous improvement" at one, two, three, six and twelve months [9]. The second study was the most difficult to interpret, assessing pain using a combination of scales for pain, function and satisfaction [8]. The criteria for improvement in this study included at least a two-point increase on each of the three scales. It was not possible to assess pain relief separately from these other, more global issues.

Function

Five of the seven studies included in this review assessed function. However, function was assessed differently in every study and used a wide variety of instruments.

While some studies used standardized instruments, others used individualized measurements of function such as walking distance tests.

In four of the five studies, improvement in function was reported following epidural steroid injection, but to varying degrees [6-8, 10]. Of the five studies, four assessed function using standardized instruments, such as the Oswestry Disability Index and the Roland Morris Questionnaire, and all reported improvement in function in at least one-third of the patients. All four studies reported an improvement in function in at least one-third of the patients. The fifth study also reported improvement in function, but did not specify the degree of improvement [12]. This was primarily due to the design of the study, which compared three groups of patients classified by their functional abilities at baseline (dysfunctional, emotional adaptors and highly functional). All three groups were reported as showing improvement at 12-month follow-up.

Two of the five studies assessed function by evaluating and/or measuring walking distances [6, 12]. The first study found a significant improvement in 64% of the patients [6] and the second study found a significant increase in walking distance at one-week follow-up, but not at one-month or three-month follow-up [12].

The study most difficult to interpret (Cooper, 2004) did not assess function alone, but as a contributor of an overall "improvement" score [8]. Measures for pain, function and satisfaction were combined. However, an overall improvement was seen in 55.8% of patients when combining the three scales.

Complications and Comorbidities

Complications and co-morbidities were rarely discussed in detail in any of the studies. For example, Barre, et al. reported no major complications in the study group following epidural steroid injection, such as infection, dural tear, or nerve root injury. It was also reported that patients with spondylolisthesis were more likely to have successful outcomes than people without spondylolisthesis. Another example of a lack of information concerning complications, was in Igarashi's prospective cohort, where it was reported that one patient experienced dural puncture and was excluded from the analysis [9]. Co-morbidities were not discussed in any of the studies.

DISCUSSION

This systematic review revealed a lack of research about clinical care for lower back pain in older adults. Deficiencies in this area of research include: 1) a small number of studies; 2) generally small sample sizes; 3) inconsistent or non-standardized instruments for measuring pain relief and function return, 4) general lack of longitudinal long-term follow-ups, 5) lack of focus on the older populations, and 6) lack of focus on lumbar spinal stenosis caused by degenerative changes. These deficiencies advocate for more studies focused on older populations. To provide evidence-based recommendations, additional studies are needed.

In current literature, specific information is lacking about pain relief and function after injection treatment in older adults. Although all the studies reviewed included patients over age 65, no results specific to elder patients were reported, which limits the ability to make conclusions or recommendations for this age group. Older adults are

often poor surgical candidates, are frequently prescribed multiple medications for other chronic diseases and are at risk of drug interactions or adverse reactions [18]. Thus, the need for better data about injection effectiveness in this important patient group is urgent. As each study reviewed included people in this age range, it would be beneficial to extract information regarding treatment for low back pain specifically in older adults, especially since lumbar stenosis is a common diagnosis among aging adults. For example, six of the seven studies reported improvement following treatment [6-11], but did not stratify the results by age group. If older patients responded differently to treatment compared to younger patients, it was not possible to make this distinction in this literature review.

The effectiveness of injection treatment for lumbar stenosis was measured using a variety of instruments designed to assess pain and function in this review. Also, the studies identified used a variety of study designs, inclusion criteria and follow-up periods. Inconsistencies in the assessment of injection treatment make it difficult to provide recommendations to primary care providers, particularly for optimal care of older adults.

Several inconsistencies were found concerning study design. The first problem with these studies was the clinical definition of lumbar stenosis, i.e., a narrowing of the spinal cord. The studies in this review identified several conditions as the cause of lumbar stenosis. For example, arthritic changes and displaced disks are both causes of lumbar spinal stenosis, but were combined in the studies. Importantly, magnetic resonance imaging was used as confirmation of the diagnosis in the majority of the studies before injection was used. The presence of pain associated with lumbar stenosis

was also commonly used as a criterion for a diagnosis. However, the underlying causes for the development of lumbar spinal stenosis were not stratified in the analyses. Future research may better assess the effectiveness of injection treatment by focusing on more specific diagnoses.

The second problem in the assessment of the degree of pain relief and functional improvement in the reviewed studies was a difference in the length of follow-up periods. Improvements were seen in all the follow-up periods, but the studies ranged from one week to one year. For the primary care provider, the recommendation of injection treatment may rely on patient preferences for either long or short term relief. For example, an inactive older adult's preferences may differ from those of a younger, more active patient. While an older patient may be focused on the next three months, a younger patient may prefer to receive treatment that will provide relief for the next five years. These differences in outlook should affect what type of treatment is recommended. Based on the findings of the studies included in this review, future research should include a more consistent range of follow-up periods to more accurately assess both the long and short term effectiveness of injection treatment.

The third problem was the lack of group-specific information that is useful to advise elderly patients. Though all the studies in this review included people over age 65, none focused on this group specifically. Since treatment for lower back pain caused by lumbar spinal stenosis has been increasing over the last fifteen years, especially in patients over age 60 years [19], more information is needed about this age group. If primary care practitioners are making decisions about follow-up care for their older

patients with lumbar stenosis, it is difficult to make assumptions about injection treatment based on the majority of these studies. It is evident from the design of these studies that a more clearly defined focus on older adults is needed for future research.

The fourth problem found in this review concerns the variety of instruments used to assess both pain and function. Because of this variety, it was not possible to combine these results to offer an overall quantitative measurement of either pain or function, thus an evidence-based recommendation cannot be formulated. However, a general improvement in function and decrease in pain was seen in all the studies reviewed. This information could be useful to the primary care provider when deciding whether injection treatment is appropriate. Although a general improvement was seen throughout the seven studies, it should be noted that the degree of improvements varied among studies. The variability was primarily due to the complexity of measuring an improvement that is self reported, such as pain and function. According to factors such as age, lifestyle, mental health and comorbidities, every patient's perception of pain and function is unique, and responses will vary. The differences in what patients consider acceptable should be considered when making decisions about follow-up care for lumbar stenosis.

While injection therapy for lumbar stenosis is a common decision in the management of lower back pain, limited data are available to date concerning treatment of lumbar stenosis by injection therapy, especially in older adults. The number of studies included in this review, though limited in number, generally do show an improvement in pain and function. However, more research into this promising procedure is necessary. Several important issues should be considered in future research. First, studies are

needed focusing on people over age 65. Since arthritis increases with age, and lower back pain is one of the most common complaints reported by older patients, more research should focus on lumbar spinal stenosis caused by arthritic changes. Of primary interest should be relief from pain, functional return, comorbidities and post-injection complications. The second issue may be on differentiating between the effects of steroid versus anesthetic injections in the diagnosis and treatment of lumbar stenosis. It may be beneficial to the patient if future injections can be specific to the diagnosis. This would be particularly beneficial to people classified as older adults, who are considered a more vulnerable population and thus more prone to complications especially from multiple medications. As only one of the included studies included a randomized control trial [12], this method may be a particularly useful approach to determining the effectiveness of specific treatment regimens. The third issue is to more clearly define assessment of functional return following treatment by injection. For the older population, this may involve an evaluation of function in terms of a less mobile and less active group. The level of function achieved following treatment should be compared to both previous function and satisfaction with function. While functional return is generally a secondary consideration to pain relief, it is an important aspect of patient satisfaction and emotional health.

No studies have specifically documented the effects of injection therapy for lumbar stenosis in older adults, over age 65. With a growing number of people in this age group, it would be beneficial to older adults if the effects of injection treatment were better understood for their age group. Although more studies have been published

focusing on injection therapy for treatment of lumbar stenosis in the last five years (as compared to the last ten years), specific information about older adults is not available to date. If future research provides information on older adults, practitioners treating people in this age group could make more informed decisions regarding optimal treatment. Older patients may experience fewer procedures and more effective pain relief for low back pain caused by lumbar stenosis. An important result would be that general practitioners treating older adults would be equipped to make more informed healthcare decisions for the treatment of lower back pain.

The problems identified about injection treatment in older patients in this review have served as an outline for the research studies conducted and described in this dissertation. There were several issues found to be problematic in past literature. These problems included small sample sizes, non-standardized instruments for measuring pain relief and functional return, inconsistent follow-up periods, lack of focus on specific diagnoses and lack of focus on older populations. These deficiencies were considered in the design of three studies. All three studies focused on patients aged 60 and over, with a specific diagnosis of lumbar spinal stenosis caused by arthritic changes. Two prospective studies used standardized instruments for the measurement of pain and function as well as consistent follow-up periods. Sufficient sample sizes for these studies, as well as one retrospective study, were computed using power analyses to ensure the detection of meaningful changes in pain and function scores following treatment. These issues were considered in the design of the studies described in Chapters 2, 3 and 4.

Figure 1.1: Search strategy for Medline

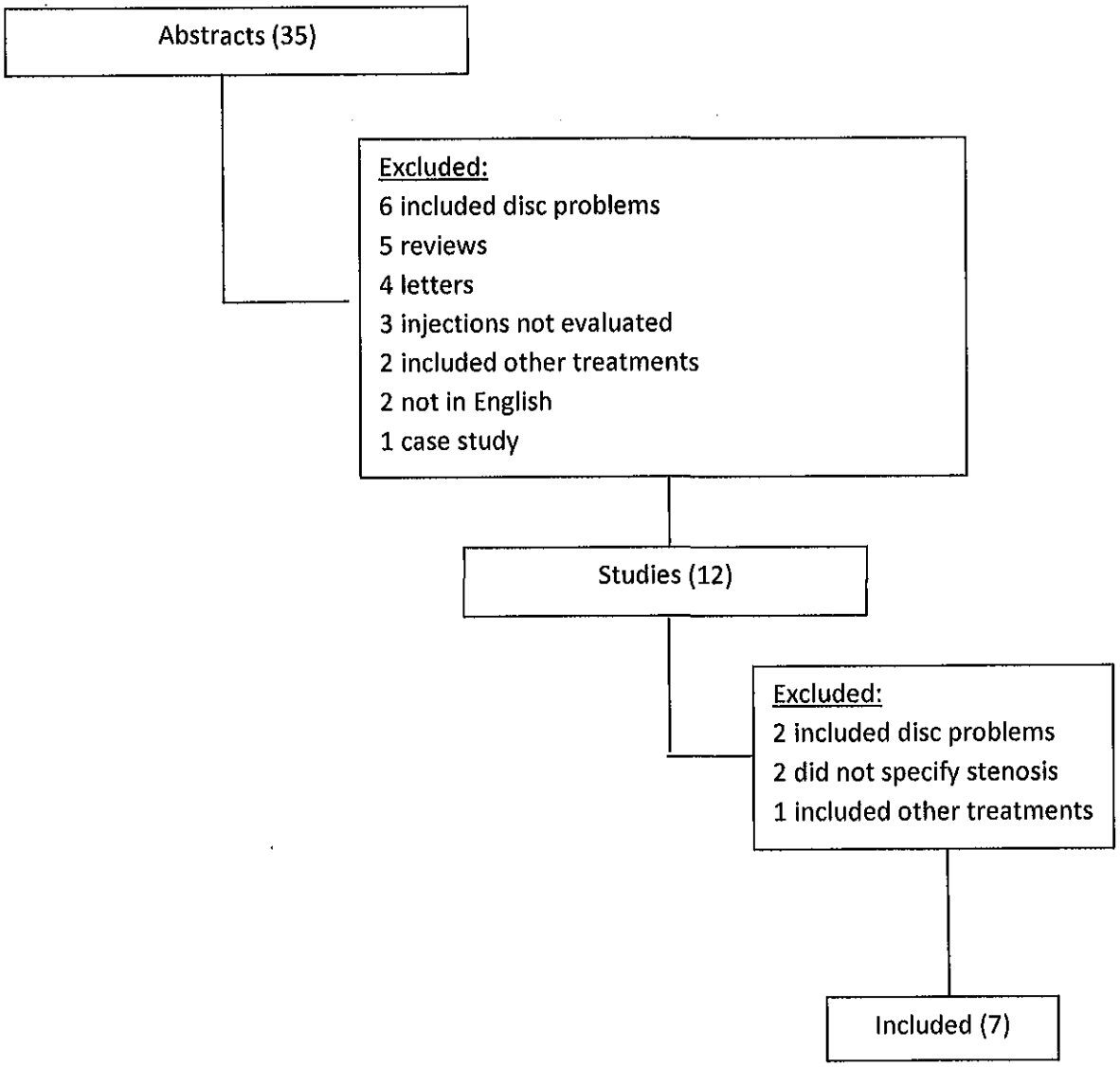


Table 1.1: Study characteristics

				Overall		
Author (year)	**N**	**Mean Age**	**Study Design**	**Pain**	**Complications Comorbidities**	**Function**
Barre (2004)	95	69	Retrospective Cohort	√	√	√
Cooper (2004)	52	69	Retrospective Cohort	√	*	√
Igarashi (2004)	58	71	Prospective cohort	√	*	*
Ng (2004)	62 55	62 40	Prospective cohort	√	*	√
Botwin (2002)	34	77 (range 62-87)	Prospective cohort	√	*	√
Rivest (1998)	21 2	54	Prospective cohort	√	*	√
Fukusaki (1998)	53	70 (A) 69 (B) 72 (C)	RCT	*	*	√

* Not included in study

Table 1.2: Outcome following treatment by injection.

	Lumbar Stenosis Diagnosis	Age range	Follow-up Period(s)	Pain Measure	Function Measure	Complications and Comorbidities	Outcome
Barre (2004)	Back or bilateral leg pain ≥ 3mos.	40 - 91	1) 1 week	Verbal Numeric Pain Scale	Roland-Morris Disability Questionnaire	None reported.	Improvement in pain Improvement in function
Cooper (2004)	1) Radiculopathy 2) Radiographic evidence	50 - 90	1) 1 week 2) 1 month 3) 3 mos. 4) 12 mos. 5) 24 mos.	Stucki Questionnaire	Stucki Questionnaire	*	55.8% showed improvement at 1 month followup 37.2% showed improvement at 1 year followup
Igarashi (2004)	1) Computed tomography 2) MRI	45 - 92	1) 1 week 2) 1 month 3) 2 mos. 4) 3 mos. 5) 6 mos. 6) 12 mos.	Visual Analog Scale	*	Accidental dural puncture reported in one patient.	Low back pain relief for 12 months
Ng (2004)	1) Unilateral radicular pain 2) MRI	*	1) 3 mos.	Visual Analog Scale	1) Oswestry Disability Index 2) Low Back Outcome Score	*	37% had ≥ 10% reduction in Oswestry Disability Index
Botwin (2002)	Lower back and radicular pain	62 - 87	1) 2 mos. 2) 12 mos.	Visual Analog Scale	1) Roland 5-point scale 2) Walking/ standing tolerance test	*	75% had ≥ 50% improvement in pain 64% ↑ walking 57% ↑ standing
Rivest (1998)	1) Computed tomography 2) MRI 3) Electromyography	17 - 86	1) 2 weeks	Visual Analog Scale	*	*	38% stenosis patients showed improvement 61% herniated disc patients showed improvement
Fukusaki (1998)	1) Plain X-rays 2) MRI 3) Computed tomography	*	1) 1 week 2) 1 month 3) 3 mos.	*	Walking distance	None reported	No significant difference between the three groups.

* = Not included in the study. MRI = Magnetic Resonance Imaging

CHAPTER 2

Return for repeat injections to treat lower back pain in older patients with degenerative lumbar spinal stenosis: A retrospective study

INTRODUCTION

Lumbar spinal stenosis (LSS) is a common condition that causes pressure on the spinal cord and nerve roots, resulting in lower back and leg pain. LSS is commonly caused by degenerative changes in older adults. Treatments to reduce pain include both surgical (laminectomy and/or lumbar fusion) and non-surgical (physical therapy, medications, injections) interventions. Lumbar surgery to treat LSS has been steadily increasing in the U.S. since 1990, especially in patients age 60 and older [19]. However, laminectomy procedures have shown as much as a 64% failure rate (defined as local tissue trauma and post-operative spinal instability) [16]. As a result, many physicians and patients choose non-surgical methods for treatment [17]. One commonly recommended treatment to alleviate symptoms for LSS is injection therapy, with medications containing steroids and/or analgesics. Since the development of fluoroscopic guidance in the mid-1990's, injections have been delivered more accurately and many patients have experienced satisfying pain relief [6]. As the proportion of older adults in the general population grows each year, it is expected that degenerative changes associated with LSS will increase as well. Older patients may likely continue to seek alternative, less invasive treatments for their lower back pain. However, much of the research to date has been conducted among younger patients with LSS [6, 14-16].

The goal of this retrospective study of medical records, was to quantify the percent of the older adult LSS population (people ≥ age 60) in the University of Massachusetts Medical Center Spine Clinic who required a second injection and to determine the mean time interval between

first and second injections. In this paper, we report on the outcomes of 100 patients (≥age 60) diagnosed with LSS, who received steroid and/or analgesic injections. These data are important when counseling patients who are considering injection therapy. To our knowledge, research on repeat injections in older adults has not been published to date.

METHODS

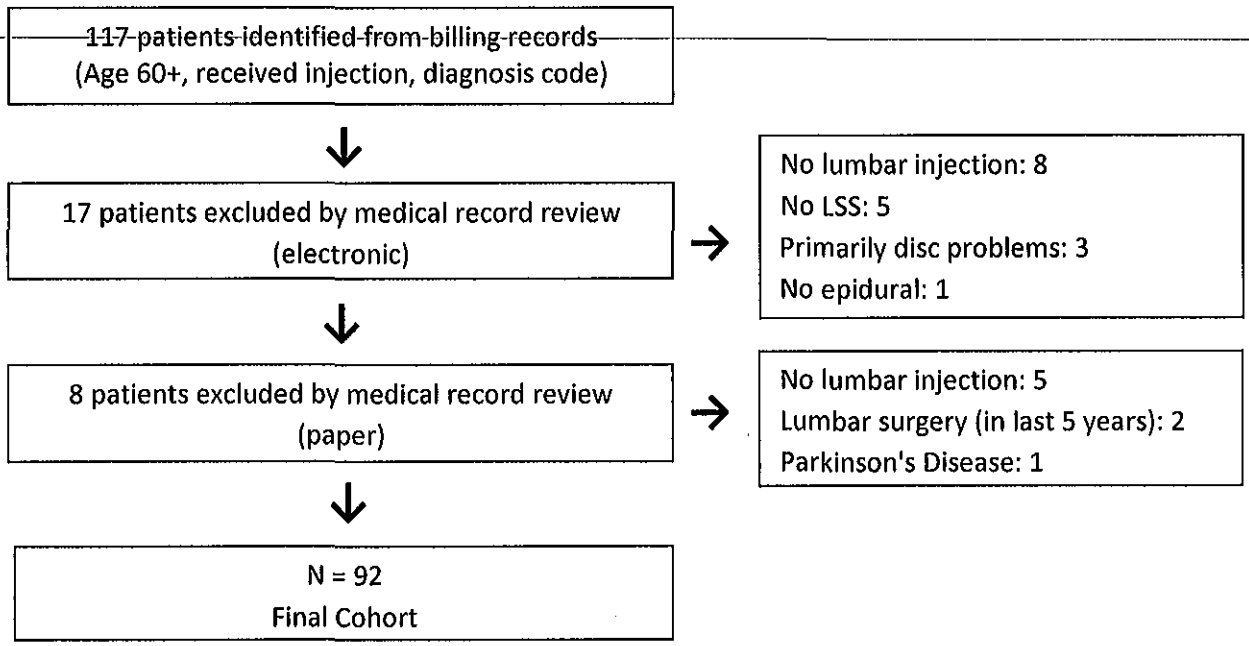
Patients

All patients who received a lumbar injection in the UMass Memorial Hospital Spine Center between June 1, 2006 and May 31, 2007 and were age 60 and over were eligible for review. Exclusion criteria included a diagnosis other than lumbar spinal stenosis (confirmed by Magnetic Resonance Imaging), a previous lumbar injection received within 6 months or lumbar surgery within 5 years of the baseline injection. Subject selection was accomplished in 2 phases. 1) Using billing records, 117 patients were identified that were age 60 or older, had received an injection between June 1, 2006 and June 1, 2007, and had been assigned a diagnosis code of 724.02 (LSS) or 724.2 (lumbago). 2) After medical record review, 17 patients were excluded for one of the following reasons; a) having received injections in locations other than the lumbar region of the spine, b) having a diagnosis other than LSS, c) having primarily disc related problems, or d) receiving an injection that was not an epidural. After paper medical record review, an additional 8 patients were excluded for having received injections in locations other than the lumbar spine, for having received lumbar surgery within the 5 years prior to their first injection date or for having a diagnosis of a musculoskeletal disorder that may conflict with injection effectiveness. The final cohort consisted of 92 patients (Figure 1).

Data Collection

A structured, standardized data collection sheet was designed to include collection of the following variables: patient name, medical record number, birthdate, gender, height, weight, race, physiatrist name, marital status, diagnosis code, Magnetic Resonance Imaging (MRI) date and location, vertabrae involved, physiatrist diagnosis and injection information (dates, anatomical location, injection type and Visual Analogue Scores). Pain level was measured by the Visual Analogue Scores (VAS) and was taken at two time points; baseline and one week following lumbar injection. MRI reports and procedure notes were reviewed for information regarding diagnosis and injection details. To address LSS severity, a co-investigator (orthopedic physician) reviewed medical records. Using methods outlined in previous literature [13] severity scores were assigned after careful review of Magnetic Resonance Images. Five variables were collected by MRI review; location of stenosis within the lumbar (level and side), number of moderate to severe levels, severity (mild, moderate or severe) and mid-sagittal diameter. Information about medical history, smoking and alcohol consumption was deemed to be inconsistent within medical records. Although these factors are potentially important, they were not evaluated in this study.

Figure 2.1: Flowchart of patient selection.



Collected data were computerized using a Microsoft ACCESS [20] database specifically designed for this study. Two techniques were used to reduce data entry errors: 1) a data entry screen using Microsoft ACCESS was designed to look identical to the data collection sheet , and 2) drop-down menus were used wherever possible. All data were entered by a trained research assistant in the Orthopedics Department, then verified by the first author (verifying every tenth record).

All variables were examined for distributional characteristics using scatter plots, means, medians and ranges. Key clinical variables derived from the data include; 1) age at first injection, 2) Body Mass Index (BMI) computed as weight (kg) divided by body height in meters squared, 3) time between the first injection and second injections (months), and 4) severity of LSS (mild, moderate, severe).

Statistical Analysis

Using the statistical software Intercooled STATA 9.0 [21], descriptive statistics including means , number and percentages of age, gender, marital status, body mass index, visual analog scores and disease severity were computed. Associations of receiving a second injection within six months of the baseline injection with gender, age, baseline VAS, BMI, marital status and LSS severity were examined using logistic regression models. Pilot data indicated second injections were most often received within six months of the first injection. Logistic regression models were used to examine this timeframe. Further, Cox Proportional Hazard Regression models were used to explore the relationship of time from baseline injection to the immediate next injection for patient characteristics.

RESULTS

The cohort consisted of 92 patients, 64% female and 59% married (Table 1). The mean age was 68 years and the mean Body Mass Index was 32.1 kg/m2. Mean baseline pain score, measured using the Visual Analogue Score, was 5.5 (SD=2.9). Magnetic Resonance Imaging (MRI) was only available for 35 patients at baseline, where 80% were classified as having LSS severity of moderate to severe and 20% were classified as mild.

Table 2.1: Patient Characteristics.

Variable	N	% (SD)
Overall	92	100
Age (years)		
Mean	68	(5.0)
Gender		
Males	33	36
Females	59	64
Marital Status		
Not Married	38	41
Married	54	59
BMI (kg/m2)		
Mean	32.0	(7.3)
VAS – baseline (1-10)		
Mean	5.5	(2.9)
VAS - 1 week (1-10)		
Mean	3.0	(3.0)
LSS Severity		
Mild	7	20
Moderate to Severe	28	80
Mid-sagittal Diameter		
Mean	11.1	(2.7)

Characteristics of patients receiving a second injection versus not receiving a second injection within six months were reported in Table 2. Of the 92 patients, 52 (57%) received a second injection within 6 months of the first, where 52% were male, 65% were between the ages of 60 and 70 years, and 65% were considered obese to morbidly obese. Chi-square tests were used to compare differences in the probability of returning for second injections between patient characteristics categories (Table 2). Returning for second injections within six months from baseline differed significantly ($p<.05$) between age groups (60-69y versus 70y+).

Table 2.2: Receipt of second injections within 6 months in lumbar spinal stenosis older patients by patient characteristics.

Variable	Categories	Received second injection within 6 months n (%)	Did not receive second injection within 6 months n (%)
Overall		52 (57)	40 (43)
Gender	Male	17 (52)	16 (48)
	Female	35 (59)	24 (41)
Age *	60-69y	41 (65)	22 (35)
	70+y	11 (38)	18 (62)
VAS (Baseline)	≤ 5	20 (54)	17 (46)
	> 5	23 (64)	13 (36)
BMI (kg/m2)	Normal (18.5-24.9)	5 (50)	5 (50)
	Overweight (25-29.9)	16 (62)	10 (38)
	Obese (30-34.9)	18 (62)	11 (38)
	Morbidly Obese (>35)	9 (60)	6 (40)
Marital Status	Married	21 (55)	17 (45)
	Not Married	23 (43)	31 (57)
LSS Severity	Mild	5 (71)	2 (29)
	Moderate/Severe	19 (68)	9 (32)

*P<.05 (based on chi square analysis to compare receipt of second injection between groups)

A statistically significant difference in rate of return for second injection was seen in the two age groups, 60-69 and 70+ (Table 3). Based on logistic regression modeling, patients age 70 and older were found to be 67% less likely to receive a second injection within 6 months of the first (OR=0.33: 95%CI; 0.13 – 0.82). When age was included in the model as a continuous variable, patients were 10% less likely to return for a second injection within 6 months of the first for every year aged over 60 (OR=0.90 (0.83 – 0.99);p<.05). This relationship was examined graphically and confirmed. Gender, baseline VAS, BMI, marital status, LSS severity and co-morbidity scores were not associated with a repeat injection within 6 months of the first injection.

Table 2.3: Unadjusted odds ratios (OR) for second injections by patient characteristics

Patient Characteristics	^OR (95% CI)
Gender (males vs. females)	0.73 (0.31 – 1.71)
Age (+1 year)	0.90 (0.83 – 0.99)*
Age (70+ vs. 60-69y)	0.33 (0.13 – 0.82)*
Baseline VAS (>5 vs.>5)	1.50 (0.59 – 3.84)
BMI (Obese vs. non-obese)	1.13 (0.46-2.79)
Marital Status (Married vs. not married)	1.09 (0.47-2.52)
LSS Severity (mild vs. moderate/severe)	0.84 (0.14-5.22)

Based on logistic regression; * p-value <.05

In a multiple regression analysis examining the same variables (Table 4), age was again found to be the only variable significantly associated with receiving a second injection within 6 months of the first. Patients age 70 and older were found to be 67% less likely to receive a second injection within 6 months of the first (OR=0.33 (0.12 – 0.94)).

Table 2.4: Adjusted odds ratios (OR) for second injections by patient characteristics.

Patient Characteristics	^OR (95% CI)
Age group (70+)	0.33 (0.12 – 0.94)*
Sex (males)	0.77 (0.28 – 2.14)
Marital Status	0.83 (0.29 – 2.35)
Baseline VAS	1.42 (0.53 – 3.79)

Based on logistic regression; * p-value <.05; LSS severity was not included in the adjusted model since data was limited.

Time between baseline and second injection was available for 65 patients and reported for each patient characteristic in Table 5. The remaining 27 patients did not receive second injections within the follow-up period, but continued to use the UMass healthcare system. Patient characteristics are compared between the two groups in Table 6 and were similar. Among the patients having a second injection, the mean time between injections was 4.8 months. Wilcoxon rank tests were computed to compare time between injections by patient characteristics. Because the cohort consisted of a high percentage of those in the morbidly obese

category, BMI groups were collapsed to morbidly obese vs. not morbidly obese. There were no significant differences between the patient characteristics categories.

Associations of any repeat injection within 6 months of the first were examined in three models and are presented in Table 7. Model 1 included as predictors age, sex, BMI, marital status and VAS. In this model, age was not a significant variable, but approached statistical significance (p=0.08). Model 2 included predictors age, sex, marital status, and VAS. Age effect again approached statistical significance (p=.06). Model 3 included predictors age, sex, BMI, marital status, VAS and an interaction term between BMI and age. The results indicated there was no interaction between BMI and age (p=0.17). The relationship between age and months between injections is shown in Figure 2.

Table 2.5: Months between first and second injections in older patients with lumbar spinal stenosis by patient characteristics.

Variable (n)	Mean (SD)	Median (range)
Overall (65)	3.7 (3.9)	2.1 (.46 – 19.9)
Gender		
Male (21)	4.2 (4.7)	2.4 (.73 – 19.9)
Female (44)	3.5 (3.5)	2.0 (.46 – 17.9)
Age		
60-70 (49)	3.7 (4.0)	2.1 (.5 – 19.9)
Over 70 (16)	3.7 (3.6)	1.7 (.46 – 12.6)
VAS - Baseline		
≤ 5 (24)	3.3 (2.9)	2.5 (.46 – 11.9)
> 5 (27)	2.9 (2.3)	1.9 (.66 – 7.9)
BMI (n)		
Normal (5)	2.6 (2.0)	1.7 (.66 – 5.6)
Overweight (20)	3.8 (4.2)	2.2 (.46 – 17.9)
Obese (21)	2.8 (2.1)	2.1 (.5 – 6.9)
Morbidly Obese (13)	5.2 (5.6)	2.4 (.86 – 19.9)
Marital Status		
Married (39)	3.4 (3.1)	2.1 (.5 – 12.6)
Not Married (26)	4.1 (4.9)	2.2 (.46 – 19.9)
LSS Severity		
Mild (6)	2.0 (2.4)	1.0 (.5 – 6.9)
Moderate/Severe (22)	3.1 (2.3)	2.3 (.46 – 8.7)

Wilcoxon Rank tests were conducted on mean time between injections between categories. No p-values were < 0.05. (BMI was evaluated as non-obese (normal to overweight) vs. obese (obese to morbidly obese).

Table 2.6: Comparison of censored and uncensored patients

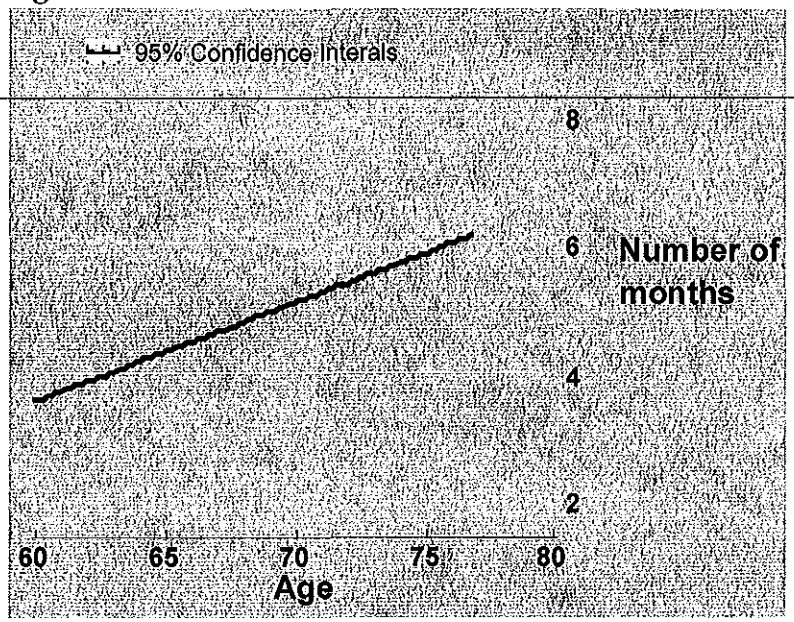
Characteristic	Uncensored n=65	Censored n=27
Age (mean (SE))	67 (.59)	69 (.99)
Female (n (%))	44 (67)	15 (56)
Married (n (%))	39 (60)	15 (55)

Table 2.7: Multi-variable adjusted rate ratios (RR) and 95% confidence intervals (CI) of time between first and second injections using a Cox Proportional Hazard Regression.

	Patient Characteristics	RR (95% CI)	p-value
Model 1	Age (70+ vs. 60-69)	0.54(0.28-1.07)	NS (.08)
	Sex (Male vs. female)	0.70 (0.38-1.29)	NS
	BMI (Obese vs. not obese)	0.91 (0.51-1.63)	NS
	Marital Status (Married vs. not)	1.00 (0.54-1.84)	NS
	VAS-Baseline (>5 vs. <5)	1.35 (0.75-2.45)	NS
Model 2	Age (70+ vs. 60-69)	0.53 (0.28-1.03)	NS (.06)
	Sex (Male) vs. female	0.80 (0.44-1.44)	NS
	Marital Status (Married vs. not)	0.92 (0.51-1.68)	NS
	VAS-Baseline (>5 vs <5)	1.34(0.75-2.37)	NS
Model 3	Age (70+ vs. 60-69)	0.52 (0.21-1.31)	NS (0.17)
	Sex (Male vs. female)	0.70 (0.38-1.29)	NS
	BMI (Obese vs. not obese)	0.89 (0.45-1.76)	NS
	Marital Status (Married vs. not)	1.00 (0.54-1.89)	NS
	VAS-Baseline (>5 vs. <5)	1.36 (0.75-2.48)	NS
	Age*BMI interaction	1.10 (0.29-4.14)	NS

Model 1: Age, gender, BMI, marital status, VAS. Model 2: Age, gender, marital status, VAS.
Model 3: Age, gender, BMI, marital status, VAS and age*BMI interaction term. NS=Not Significant

Figure 2.2: Number of months between first and second injection by age



DISCUSSION

The overall finding of this study provides the orthopedic community with three valuable pieces of information. 1) More than half of all patients over age 60 will probably need a second injection within 6 months of the first injection, 2) Patients over age 60 will likely feel pain relief for up to 5 months, and 3) Patient characteristics such as age and BMI may play a part in how well they respond to treatment. In this cohort, the majority of the patients received a second injection within six months (57%). However, when stratified by patient characteristics, there were no significant differences between patient sub-groups except by age. The main finding of this study was a significant difference in patients by age, where older patients were less likely to return for a second injection compared to younger patients. In this clinic, patients were encouraged to make an appointment for another injection if the first injection did not provide enough pain relief. Due to the retrospective design of this study, the reason for not returning within six months could not be determined. There are a number of reasons older patients may

not return as soon as younger patients for a second injection including mobility, health insurance and social support. Though it was not possible to collect information on mobility or details regarding health insurance, social support might be measured using marital status as a surrogate. Marital status was not associated with injection treatment effectiveness. However, other forms of social support were not available for this study and may have affected the association. For example, if younger patients have more support from family members other than spouses, they may be more likely to receive help in returning for a second visit as compared to older patients.

Another consideration for the difference could be due to the small sample size, where only a third of all patients were aged 70 and older (n=29). Future research studies may benefit by focusing on this age group to better understand the differences in receipt of repeat injections. A further consideration is the way in which patients were categorized. Patients categorized as "not receiving a second injection within six months" (Table 2) included both patients who *did* receive a second injection after six months (n=13) as well as patients who *never* received a second injection at all (n=27). This approach effectively answers the question about whether a patient returned for a second injection within six months or not, but it should be noted that the comparison group contained a mixed sample. The analysis was repeated for patients who required a second injection within 12 months and similar results were seen.

The study found that the amount of time patients may expect pain relief, as measured by time elapsed between first and second injection, may vary by several patient characteristics though none of these reached statistical signficance. In the entire cohort, patients did not seek a second injection for an average of almost 5 months. Differences between groups by various patient characteristics were not significant. However, only about two-thirds of the cohort had received a second injection (n=65). It should be noted that more than half of all patients in this

cohort were obese to morbidly obese and the vast majority were in the overweight, obese or morbidly obese categories (87%). The large proportion of patients qualifying as morbidly obese (13%) had an average of 5.2 months between injections, compared to approximately 3 months for lower BMI patients, although this was not significant. The reasons for not returning sooner could be similar to older patients, such as problems with mobility and social support.

Another goal of this study was to explore patient characteristics that may be related to pain relief and return for a second injection. As described previously, the patient characteristics noted as potential influences in this study are age and Body Mass Index. Though this study does not have the power to detect statistically sound differences between patient groups, the results contribute to the body of research building for injection treatment. The differences found will inform power analyses for further research in these areas.

Another limitation of this study was the lack of information about LSS severity. Since MRI records were only available for about one-third of the patients, sample power was inadequate for assessing how LSS severity may have affected treatment. In a sub-analysis, VAS pain scores were consistent with LSS severity, where baseline means were considerably higher in more severe cases (7.3) versus milder cases (5.2). In addition, LSS severity was tested in the adjusted logistic regression model, but did not show significance. It is not clear if a larger sample would have yielded similar results. Therefore, it would benefit future research to collect information on LSS severity to more adequately assess injection treatment effectiveness.

Lack of information about patients who did not receive a second injection within the study data collection time period was another limitation. It is unclear if these patients received a second injection after data collection was completed, received an injection elsewhere or never received a second injection. Since nearly one-third of the study patients were considered

uncensored in this study (27/92), it may be useful for future research to extend the follow-up period to collect additional information on those lost to follow-up. However, in this study, censored and uncensored patients were compared and their characteristics were similar. In addition, all 27 patients were continued users of the UMass healthcare system, so it is unlikely they received second injections at other institutions.

Further investigation is needed in this age group to determine why younger patients return sooner than older patients. Both physical and mental differences could exist between the two age groups, such as a larger desire for an active lifestyle in the younger group. In addition, this cohort included only patients over age 60, but the vast majority ranged from overweight to morbidly obese. The profile of patients over age 60 with lower back pain who seek injection treatment is interesting and warrants further investigation, but is not within the scope of this research. However, as with older patients, people with higher BMI's should be more carefully examined in future research to determine the reasons a second injection is not sought as soon as in lower BMI patients.

As the proportion of older people in the general population continues to increase over the next two decades, clinicians will likely seek information about how to best treat their lower back pain. If injection therapy continues to be the preferred treatment in this age group in the future, further research is needed for clinicians to better understand how to achieve the best outcome.

CHAPTER 3

Functional improvement after injection treatment in older adults with lumbar spinal stenosis

INTRODUCTION

Lumbar spinal stenosis (LSS) is a common condition that causes pain in the lower extremities and/or back. LSS is most often caused by degenerative changes in older adults, resulting in compression of nerve roots and narrowing of the lumbar spinal canal. In 2004, thirty percent of Americans 65 years and older reported symptoms of lower back pain [1]. Treatment to alleviate pain has historically included both surgical and non-surgical approaches. Due to risks associated with lumbar spinal surgery, especially in aging adults [17], many physicians and patients choose non-surgical methods of treatment. One commonly recommended treatment to alleviate symptoms for lumbar spinal stenosis is injection therapy, with medications containing steroids and/or analgesics. As the population ages, complaints about back pain caused by LSS will likely rise, and effective low-risk procedures to alleviate pain will be in increasing demand. However, there is limited information about injection treatment in older adults diagnosed with LSS. Studies published to date have included patients with diagnoses other than LSS, included a wide range of ages, and used a number of different measurement tools for both pain and function [7-12, 22]. Measurement of functional return following treatment has been particularly inconsistent in previous literature. A wide variety of instruments, including surveys and walking tests have been used to measure function in past studies. In this study, functional return has been examined in adults age 60 and over using both a global physical health measurement tool (Short Form-36/PCS) and a spine specific measurement tool (Oswestry Disability Index). Older patients scheduled to receive a lumbar injection were prospectively enrolled and followed for three

months after their initial injection. Questionnaires were completed at baseline, one month and three months post injection to measure physical function.

METHODS

Patient Population

All patients ≥ 60 years old, who had been diagnosed with lumbar spinal stenosis and were scheduled to receive any injection for lower back pain at the Spine Center were eligible. Potential study patients were identified by reviewing Injection Room schedules two weeks in advance. Diagnosis of LSS was confirmed by the primary investigator using Magnetic Resonance Imaging reports and clinical notes. Exclusion criteria were receipt of a previous injection in the lumbar within the past 6 months; lumbar surgery within the past two years; history of lumbar fracture, malignancy or infection; inability to provide informed consent due to dementia or cognitive impairment; co-existing musculoskeletal conditions that would negate functional improvement with injection (e.g., severe Parkinson's disease, or hemiparesis) or amputation of any lower extremity. All patients who agreed to participate provided signed consent forms and completed one general health questionnaire and one questionnaire specific to back pain before their scheduled injections.

Approximately three weeks following baseline injection, patients were mailed one-month follow-up questionnaires. If the questionnaires were not returned within two weeks, the participants were contacted by phone. Two additional calls were made if the surveys were still not returned. The process was repeated for the three month follow-up period. This study was approved by the Institutional Review Board (IRB) at the University of Massachusetts Medical School.

Treatment

Epidural Steroid Injection Procedure:

Patients of two physiatrists were included in the study. One physiatrist administered injections to 93.5% of patients (n=58). In the procedure room, the patient was placed in a prone position. The skin over the intended interlaminar target site was marked and prepped in the usual sterile fashion. The skin and subcutaneous tissue were anesthetized with 1% lidocaine mixed with sodium bicarbonate 8.4% (10:1). The tip of a 20-gauge, 3.5-inch Tuohy spinal needle was advanced under intermittent fluoroscopic guidance towards the target. Loss of resistance with air was used to identify the epidural space. After negative aspiration for blood and cerebrospinal fluid, Isovue was injected to confirm epidural placement. Subsequently, 5 mL of injectate (1 mL Triamcinolone Acetonide (40 mg/mL) and 4 mL 0.5% preservative-free Xylocaine) was administered. The needle was removed. (For multiple levels, 5 mL of injectate was distributed equally between levels injected. For caudal injections, 10mL of injectate (1 mL Triamcinolone Acetonide (40 mg/mL), 5 mL preservative-free normal saline, and 4 mL preservative-free 0.5% Xylocaine) was slowly administered without resistance).

Outcome Measures

The primary outcome measures used for this study were the paper and pencil versions of the Short Form-36 (SF-36 version 2)(Ware 1993) and the Oswestry Disability Index [23]. SF-36 surveys were scored using Quality Metrics SF-36 scoring software by a research assistant. Training to use the scoring software was given by the orthopedics department research coordinator. Raw data from Oswestry surveys were entered into an ACCESS [20] database form by the research assistant, then checked and scored after transfer into an EXCEL [24] spreadsheet by the primary investigator. All survey scores were manually entered into an ACCESS database

form by the research assistant and every fifth record was checked for accuracy by the primary investigator.

Short Form-36 (SF-36)

The SF-36 Questionnaire is a multi-purpose 36-item questionnaire used to assess functional health and well-being. It is one of the most frequently used questionnaires to assess health related quality of life in patients with back pain [25]. The SF-36 has been validated [26] and compared to the Oswestry Disability Index in evaluating function in patients with lower back pain in a 2006 study by Ferrer [27]. It has been used in large-scale studies examining musculoskeletal issues, including a prospective study by Zanoli examining 451 patients with degenerative lumbar spine disorders [25]. Also, the SF-36 was used by Vogt et al., in the evaluation of 5,995 men 65 years and older in the Osteoporotic Fractures in Men Study [28].

The questionnaire represents multiple indicators of health including eight components. Four of these components relate to physical health and produce the measure *Physical Component Summary* (PCS). The remaining four components relate to mental health and produce the *Mental Component Summary* (MCS). In this study, two components were used; the PCS (as a primary outcome) and the MCS (as a covariate). The PCS was presented as a global health measure of function. Scores range from 0 (poor health) to 100 (excellent health).

Oswestry Disability Index

The Oswestry Disability Index (ODI) is a one of the most commonly used tools for measuring disease-specific functional ability in patients with spinal disorders. It is considered the "gold standard" for evaluating function in patients with low back pain [29]. The ODI was presented as a spine-specific measure of function. Scores range from 0 (excellent function) to 100 (poor function).

Covariates Measured

To assess physical attributes that could affect the response to treatment for pain and function, information about gender, age, body mass index (BMI), hip or knee replacement surgery history and co-morbidities was collected. Co-morbidities were scored using the Charlson Comorbidity Index (CCI) [30]. The CCI includes 19 co-morbidities, selected based on their association with mortality. It includes conditions related to cancer, diabetes, heart disease, liver disease, renal disease, chronic pulmonary disease and others. Following retrieval of diagnosis histories using electronic medical files, the CCI questionnaire was completed by the principal investigator. Results were verified by a dedicated orthopedic research resident. Medical records were also used to collect information on patient history of hip or knee replacement surgery to adjust for other lower extremity arthritic changes common in this age group and were included in the analysis.

To adjust for other pain control medications that may interfere with injection treatment, Information about narcotic use was also collected. Ethnicity information was not consistently reported in patient files and thus was not included in the analysis.

In this study, all variables were collected and analyzed as moderators (pre-treatment). However, consideration was given to two variables that may have had an effect as mediators

(post-treatment); narcotics use and baseline emotional health. As a pain management medication, narcotics use could have had an effect on pain receptors, but not on inflammation. Since narcotics use was not collected after treatment, this was a relationship that was not possible to consider in this analysis. Baseline emotional health may also have had an effect as a mediator as well as a moderator. However, past literature in musculoskeletal research suggests that emotional health is a moderator, that dampens the self efficacy leading to function. Therefore, this variable was collected and analyzed as a moderator in this study.

Data Collection

Demographic information was collected by the primary investigator using hospital administrative data and medical records. Survey scoring was accomplished using Quality Metrics scoring software for the SF-36 survey, and EXCEL for the Oswestry Disability Index. A data entry program was developed using ACCESS and data were entered by a research assistant and the primary investigator. Data entry was verified by reviewing every fifth record and no errors were found.

Analytic Plan

Descriptive statistics summarize patient characteristics such as gender, baseline emotional status (MCS), BMI, co-morbidities, narcotic use and history of total hip or knee replacement surgery (THKR). See Table 1. Baseline MCS and BMI were transformed to categorical variables. For categorical variables (gender, baseline MCS, BMI, co-morbidities, narcotics and THKR), numbers and percentages were presented. Age was presented as a continuous variable with mean, standard deviation and range. T-tests compared physical function between baseline and one month and between baseline and three months for each patient characteristic category (i.e. gender, age 60-69, age 70+, etc.). See Tables 2 and 3.

Differences in function score changes among patient categories (i.e. BMI groups) were assessed using analysis of variance tests. Significant variables in the univariate analysis were entered into the multivariate model. Change in function was examined in a series of linear mixed effects models. The mixed effects model assumes that repeated measurements in the same individual are not independent and allows individuals to have unequal numbers of observations. In this study, the outcome measure was collected at three timepoints, and some outcome data and covariate information were missing. The linear mixed effects model compensated for these missing data. The fixed effects portion of the model consisted of the variables that were significant in the univariate analysis (analysis of variance). The random effects portion of the model consisted of a random intercept only. This term accounts for between-subject variation. For example, in this study, baseline measurements of function were analyzed as separate values for each patient, rather than as a mean. Unconditional models (fixed time) and conditional models (fixed time, BMI, MCS, age, gender) were compared to determine changes in variance after the addition of variables to the model. Akaike's information criterion was used to assess goodness-of-fit between the models.

All variables in the analysis were also tested for an interaction with time (age, gender, baseline emotional health, BMI, co-morbidities, narcotic use, hip or knee replacement). Likelihood ratio tests were used to compare models with and without time/variable interactions. Test results producing significant p-values ($p<.05$) indicated time interactions were present and were included in the final model. By adding variables into the model individually, potential interactions between variables were also evaluated and significant interactions were included in the final model. Model assumptions of linearity, normality, independence of errors, and homoscedasticity of errors were examined graphically and analytically and were adequately met.

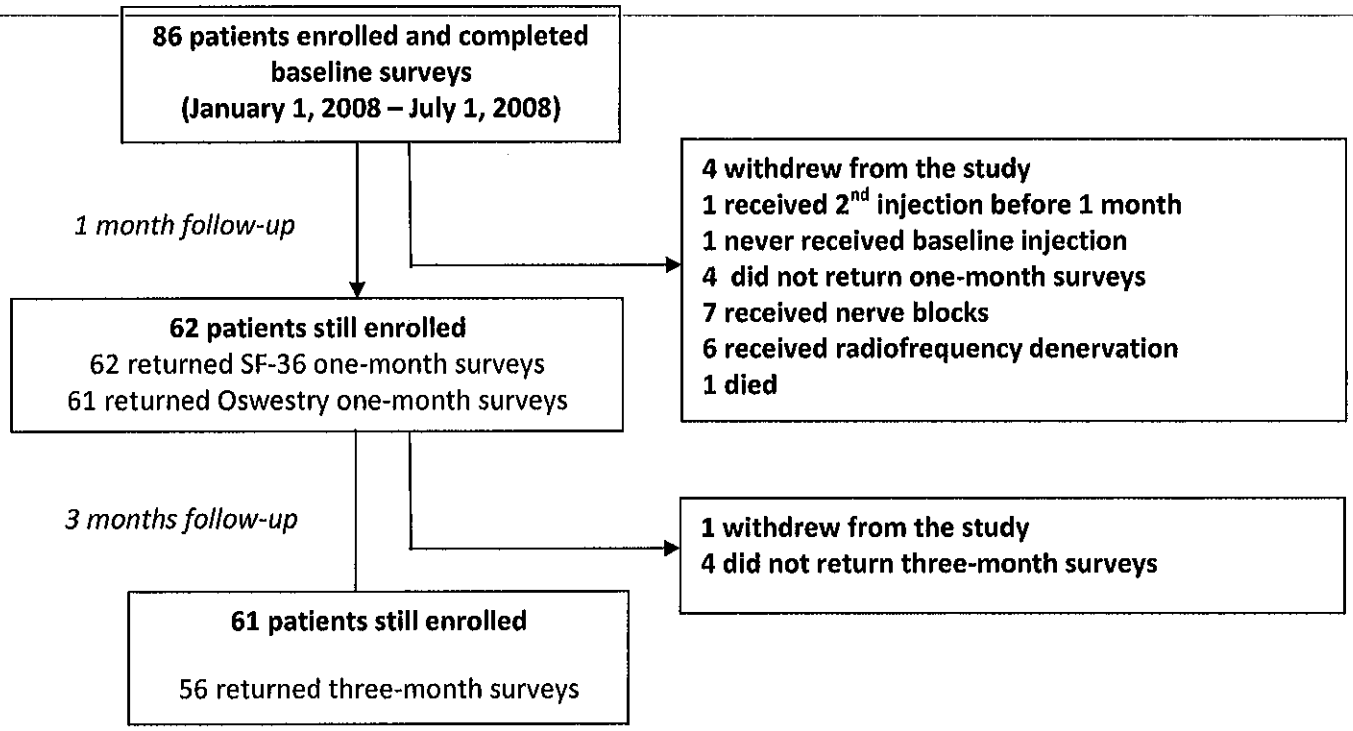
ACCESS files were exported using StataTransfer [21] for statistical analyses using Intercooled STATA 9.0 [21]. All available data from all participants were used, as long as at least one follow-up survey was returned.

RESULTS

Eighty-six patients were initially enrolled and completed baseline SF-36 and Oswestry Disability Index questionnaires administered by the primary investigator from January 1, 2008 to July 1, 2008. All patients signed study consent forms approved by the IRB. Participants were followed at one month and at three months following baseline (Figure 1). At one month, 4 participants withdrew from the study, 2 were dropped from the study (for having a second injection before follow-up (n=1) or for never having the first injection (n=1), 4 did not return the first follow-up surveys, 7 received nerve blocks, 6 received radiofrequency denervation and 1 died. Of the initial 86 participants, 62 were still enrolled after one month, 61 returned SF-36 surveys and 61 returned Oswestry surveys. At three months, 1 withdrew from the study and 4 did not return the second follow-up surveys. At the end of the second follow-up period, 61 participants were still enrolled and 56 returned three-month surveys. All patients remaining in the study received epidural steroid injections.

The mean age of participants was 74 (SD=8.1, range 60 to 90), 68% were female, 60% had high baseline emotional health (MCS≥50) and 44% were obese to morbidly obese (BMI≥50). See Table 1.

Figure 3.1: Patient enrollment flow



Change in SF-36 PCS and Oswestry scores were tabulated in Tables 2 and 3. Significant improvement was found at one month follow-up in both survey results. SF-36 PCS scores showed a 3.3 point improvement (SD=6.3; $p \leq .05$) and the ODI showed a 3 point improvement (SD=11.2; $p < .05$). Patient characteristics showing significant improvement ($p < .05$) at one month were age 60-69, were female, had high baseline emotional status (MCS$\geq$50), had normal weight, had no co-morbidities or had never had hip or knee replacement surgery. No significant improvement was found at three months follow-up in either PCS (p=.09) or ODI (p=.27). Means of function scores for both PCS and ODI are presented in Figure 2.

Higher baseline emotional status was the only characteristic that was associated with improvement in function at three months, where PCS scores showed a 3.6 point improvement over baseline (SD=7.9; $p < .05$). A one-way analysis of variance model (ANOVA) was used to compare PCS and ODI score means between group categories (i.e. male vs. female) at both one and three months (Tables 2 and 3). ODI scores differed significantly ($p < .05$) between age, BMI and co-morbidity categories. PCS differed significantly between baseline emotional status categories. Function score means for both PCS and ODI by baseline emotional status categories are presented in Figure 3.

Results from a mixed effects model analysis are presented in Tables 4 and 5. Only variables found to be significant in the univariate (unadjusted) analysis (ANOVA) and identified variable interactions were included in the multivariate (adjusted) analysis. To account for small sample size, body mass index categories were collapsed to two categories, obese and non-obese. Co-morbidities were also collapsed from four categories to two categories (co-morbidities versus no co-morbidities). The PCS scores among baseline emotional health groups showed an interaction with time. Therefore, an interaction term (baseline MCS/time) was also included in

the model. Using PCS scores, comparison of covariance estimates of the conditional model showed a small improvement in goodness of fit (0.18%, of additional variance explained for emotional health; likelihood ratio test, p-value<.05) when compared to the unconditional model (time alone). Usng Oswestry scores, comparison of covariance estimates of the conditional model showed a small improvement in goodness of fit (2.1%, of additional variance explained for emotional health; likelihood ratio test, p-value<.05) when compared to the unconditional model (time alone).

After analysis, the only variable showing significance was baseline emotional health. Function scores were significantly improved at both timepoints. In patients with high baseline emotional health, PCS function scores increased by 6.1 points from baseline to one month and by 4.6 points from baseline to three months, as compared to patients with low emotional health. Changes in the Oswestry also showed improvement for patients with high baseline emotional health, but did not show an interaction with time. Oswestry scores improved by 17.8 points over the three months follow-up period for patients with high baseline emotional health (MCS $\geq$ 50).

Table 3.1: Patient characteristics at baseline

Characteristic	N	%	SF-36 PCS Baseline Mean (SD)	Oswestry Baseline Mean (SD)
Total	65	100	28.2 (7.6)	50.6 (14.0)
Age				
Mean	74			
SD	8.1			
Range	60-90			
Gender				
Male	21	32	28.5	45.6 (11.3)
Female	44	68	28.1	58.0 (14.7)
Baseline emotional status (SF-36/MCS)				
Low (< 50)	26	40	28.5	60.2 (12.9)
High (≥50)	39	60	28.1	44.2 (10.8)
Body Mass Index (kg/m^2)				
Normal Weight (<25)	14	25	29.2	49.8 (13.2)
Overweight (25-29)	17	31	28.8	48.4 (17.1)
Obese (30-34.9)	12	22	26.0	50.1 (15.3)
Morbidly Obese (>35)	12	22	25.4	55.7 (12.1)
Number of Co-morbidities				
0	31	48	29.1	51.1 (14.7)
1	10	15	21.3	50.2 (11.0)
2	11	17	29.4	49.0 (16.2)
≥3	13	20	30.5	51.1 (13.9)
Narcotic Use				
Yes	16	30	26.6	58.9 (12.8)
No	38	70	28.4	47.4 (13.3)
Hip or Knee Replacement				
Yes	11	20	27.1	49.6 (17.4)
No	43	80	28.0	51.1 (13.3)

Table 3.2: Change in SF-36 PCS from baseline to one month and baseline to three months.

Patient characteristics	Baseline to 1 month change (mean, SD) N=61	p	Baseline to 3 months change (mean, SD) N=56	p
Total (n=56)	3.3 (6.3)	<.05	1.6 (7.3)	.09
Gender				
Male	2.8 (6.7)	.09	2.5 (8.1)	.18
Female	3.6 (6.1)	<.05	1.2 (6.9)	.30
Age				
60-69	3.8 (6.4)	<.05	1.9 (8.0)	.30
70+	3.1 (6.3)	<.05	1.5 (6.9)	.20
Baseline Emotional Status (SF-36/MCS)		*		*
< 50	.16 (5.3)	.88	-1.6 (4.6)	.12
≥ 50	5.6 (5.9)	<.05	3.6 (7.9)	<.05
BMI				
Normal weight	3.9 (4.8)	<.05	-1.2 (7.2)	.55
Overweight	0.4 (6.9)	<.05	1.5 (8.8)	.52
Obese	6.9 (5.4)	.10	5.8 (6.6)	<.05
Morbidly obese	4.4 (7.9)	.11	3.2 (6.7)	.21
Comorbidities				
0	3.3 (6.0)	<.05	0.3 (5.8)	.78
1	6.0 (6.2)	<.05	9.2 (6.7)	<.05
2	4.9 (6.2)	<.05	-1.2 (9.3)	.69
≥3	4.7 (6.5)	.80	.38 (4.8)	.80
Narcotic Use				
Yes	3.7 (6.5)	<.05	1.6 (6.6)	.36
No	4.1 (5.9)	<.05	1.6 (8.4)	.29
Hip or Knee Replacement Surgery				
Yes	4.2 (5.0)	<.05	3.2 (8.0)	<.05
No	3.9 (6.4)	<.05	1.2 (7.8)	<.05

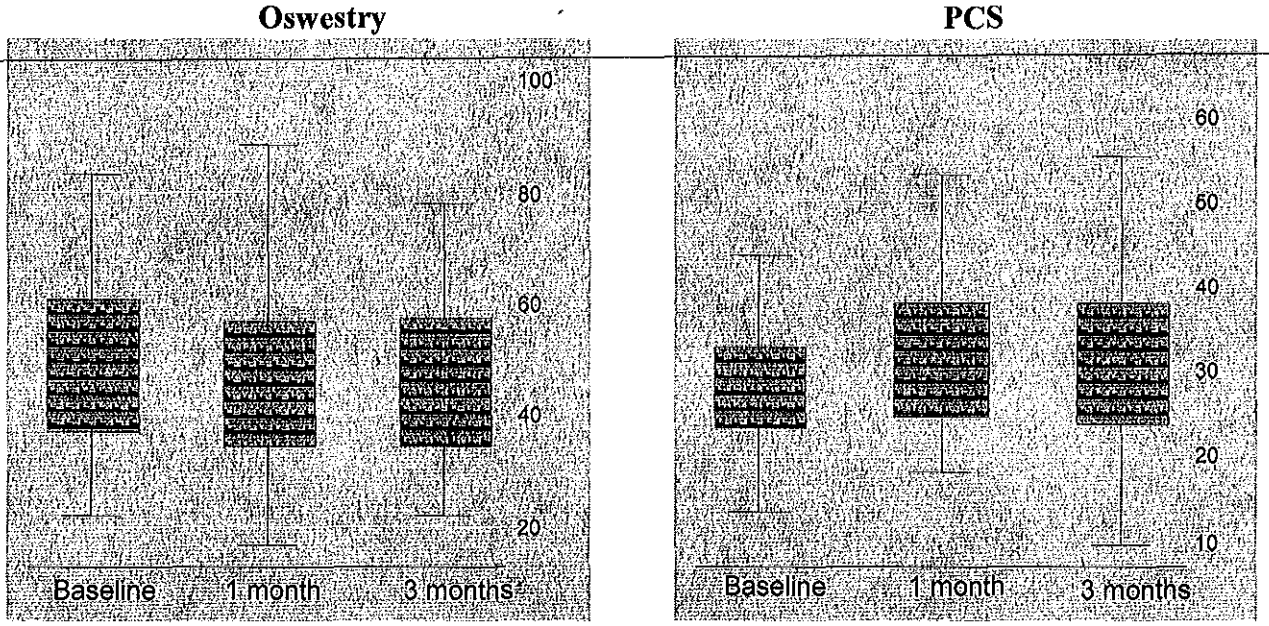
P-values represent t-test results comparing baseline and follow-up scores;
One month change in pain = 1 month SF-36 PCS score – baseline SF-36 PCS score;
Three month change in pain = 3 month SF-36 PCS score – baseline SF-36 PCS score;
* One way ANOVA p-values ≤ .05 comparing variable categories (i.e. male vs. female)

Table 3.3: Change in Oswestry scores from baseline to one month and baseline to three months.

Patient characteristics	Baseline to 1 month change (mean, SD) N=62	p	Baseline to 3 months change (mean, SD) N=56	p
Total	-3.0 (11.2)	<.05	-1.4 (9.5)	.27
Gender				
Male	-0.9 (10.8)	.70	-.79 (8.2)	.67
Female	-3.9 (11.5)	<.05	-1.7 (10.2)	.30
Age		*		
60-69	-6.8 (12.9)	<.05	-1.9 (10.3)	.41
70+	-0.8 (9.7)	.59	-1.2 (9.2)	.45
Baseline Emotional Status (SF-36/MCS)				
< 50	-1.2 (11.1)	.59	-1.1 (8.4)	.55
≥ 50	-4.4 (11.3)	<.05	-1.6 (10.2)	.35
BMI		*		
Normal weight	-5.8 (9.6)	<.05	-2.5 (12.1)	.46
Overweight	3.4(10.4)	.20	-.66 (8.0)	.76
Obese	-2.4 (6.5)	.24	.97 (9.6)	.73
Morbidly obese	-6.4 (12.6)	.12	-3.1 (7.8)	.29
Comorbidities		*†		
0	-6.6 (12.6)	<.05	-3.4 (8.8)	.06
1	-1.4 (9.2)	.65	0.6 (6.6)	.78
2	-0.9 (8.6)	.74	4.0 (11.8)	.30
≥3	2.0 (9.8)	.48	-3.7 (9.8)	.24
Narcotic Use				
Yes	-6.9 (11.8)	<.05	-4.2 (7.8)	.65
No	-3.4 (10.9)	.06	.17 (9.9)	.23
Hip or Knee Replacement Surgery				
Yes	-2.7 (10.5)	.40	1.3 (9.1)	.40
No	-4.9 (11.4)	<.05	-1.9 (9.6)	.96

P-values represent t-test results comparing baseline and follow-up scores;
1 month change in pain = baseline Oswestry - 1 month Oswestry (62 respondents);
3 months change in pain = baseline Oswestry - 3 month Oswestry score (56 respondents);
* One way ANOVA p-values ≤ .05 comparing variable categories (i.e. male vs. female)
† Co-morbidities significant when analyzed as yes/no

Figure 3.2: Mean function scores at baseline, 1 month and 3 months



Note: Better function is indicated by lower Oswestry scores and higher PCS scores

Table 3.4: Predictors of change in function (PCS) over 3 months (multivariable analysis).

Patient Characteristics	PCS β (95%CI)
Baseline MCS (<50)	
Change from baseline to 1 month	0.24 (-2.85, 3.33)
Change from baseline to 3 months	-1.32 (-4.70, 2.04)
Baseline MCS (≥50)	
Change from baseline to 1 month	6.11 (3.60, 8.63) *
Change from baseline to 3 months	4.60 (2.02, 7.18) *

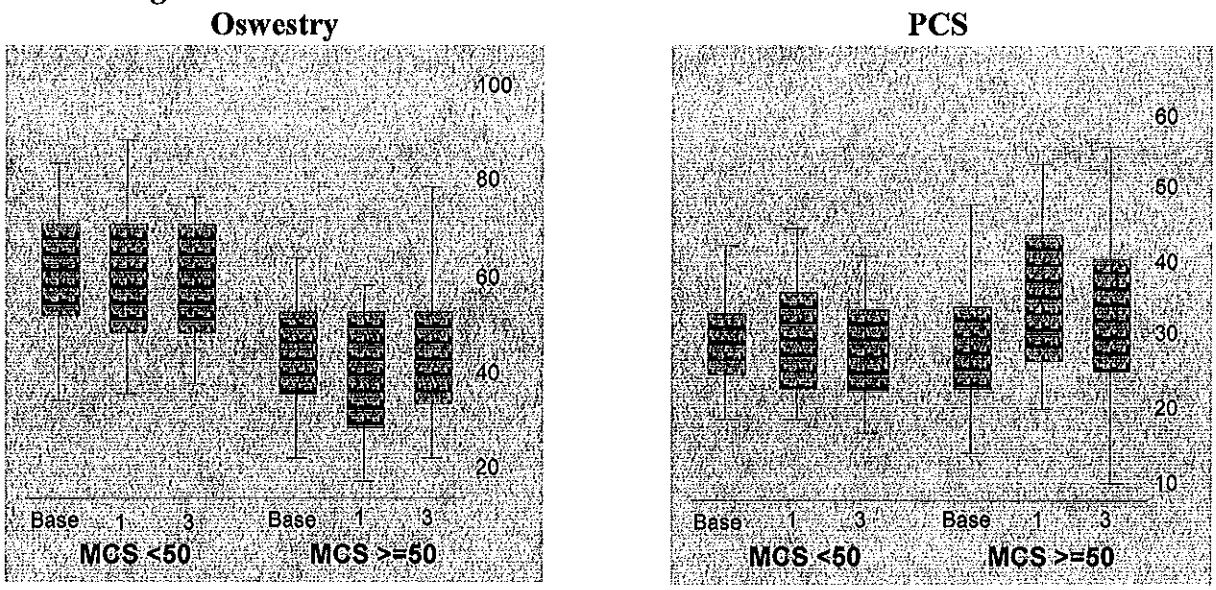
Based on mixed effects model analysis; * p<.05; Adjusted for age, BMI (obese vs. non-obese), gender and baseline MCS/time interaction.

Table 3.5: Predictors of change in function (Oswestry) over 3 months (multivariable analysis).

Patient Characteristics	Oswestry β (95%CI)
Baseline MCS (<50)	referent
Baseline MCS (≥50)	-17.8 (-23.60, -11.91) *
BMI (obese vs. non-obese)	0.08 (-5.46, 5.62)
Gender (males vs. females)	-3.64 (9.99,2.70)
Age (60-69y vs. 70+y)	4.63 (-0.94, 10.2)
Co-morbidities (yes vs. no)	3.92 (-1.58, 9.43)

Based on mixed effects model analysis; * p<.05; Adjusted for age, BMI (obese vs.non-obese), comorbidities (Y/N), and gender.

Figure 3.3: Mean function scores at baseline, 1 month and 3 months by baseline emotional health categories



DISCUSSION

This study showed that in patients over age 60 with lumbar spinal stenosis, injection treatment was associated with increase in function at both one and three months after treatment. Spine specific functional return, as measured by the Oswestry Disability Index, was significantly associated with high baseline emotional health at both one and three months. Age, BMI and the

coexistence of co-morbidities were also possible predictors of functional return but were not significant in the adjusted analysis.

Previous literature has shown injection treatment to be associated with reducing pain and increasing function in patients with lumbar spinal stenosis (Botwin 2003, Barre, Cooper, Igarashi, Ng, Rivest, Fukusaki). The results of this study support those findings, but more specifically, within older adults. In addition, high baseline emotional status has been associated with an increase in function in previous studies concerning treatment for other musculoskeletal disorders including knee replacement surgery (Ayers) and hip replacement surgery (Bischoff-Ferrari). Within older adults receiving hip surgery, good mental health status has also been associated with increased function (Travis). This study supports these findings as well. A positive response to musculoskeletal treatment in older patients with good baseline emotional health may be due to a greater adherence to post-treatment rehabilitation, a stronger social support network or a healthier lifestyle.

Response to injection treatment has not been well studied in older adults. However, this study showed a more positive response to treatment in patients age 60 to 69 compared to patients 70 and older one month after treatment. In a previous study examining hip replacement surgery (Bischoff-Farrari), age was not considered a significant factor for functional improvement. However, several physical problems commonly associated with geriatric patients including history of falls, decreased balance, vision and hearing were significant correlates of reduced function after hip surgery. Thus, these physical limitations could likely have influenced the response of those in the older patient group in our study.

Absence of co-morbidities was associated with greater functional gain following treatment in this study. This is consistent with previous research where the presence/absence of

co-morbidities was associated with variations in functional improvement [24]. The presence and number of co-morbidities in patients receiving treatment may be particularly important in older adults. This group may likely be more vulnerable to co-existing illnesses and therefore respond to treatment differently. For example, increased medication use, reduced activity and reduced immunity to common illnesses could affect response to injection treatment for lower back pain.

The primary limitations of this study were relatively small sample size and a short follow-up period. However, sample size was adequate to determine that significant functional improvement did occur following treatment in older patients. Future research should include longer follow-up periods as well as larger study sample sizes to further explore this relationship as well as age differences, the co-existence of co-morbidities and BMI.

Additional limitations include measurement of co-morbidities and stenosis severity. Measurement of co-morbidities was accomplished using the Charleson Comorbidity Index. This tool did not include minor conditions that may have had impact on treatment response. As this study showed a potential relationship between co-morbidities and functional gain, future studies may use a more comprehensive tool to measure co-morbid conditions, especially in older adults. Stenosis severity has been documented in previous studies using Magnetic Resonance Imaging (MRI) films for measurement [25-27]. Films were unavailable at the time of this study, and severity was not documented in the majority of patients. However, MRI reports were available and reviewed to confirm diagnosis. Reports that indicated disc related LSS as being the primary diagnosis were not included in the study. Future studies should verify access to films upon subject enrollment to ensure collection of severity information.

Another limitation of this study is the absence of a comparison group. The ideal comparison group for this treatment would be the use of a placebo. Due to the invasive nature of

injection treatment, and the ethical considerations of subjecting patients to a potentially useless treatment, a randomized control design would be difficult if not impossible. Another comparison group could consist of patients who received another treatment, such as surgery. Again, randomizing patients to an even more invasive procedure such as surgery would also pose many problems. Lastly, another comparison group could have consisted of patients who did not receive treatment. However, this study consisted of patients with lumbar spinal stenosis primarily caused by degenerative arthritis. As degenerative arthritis is a condition that does not improve on its own, we would expect a group without treatment to remain unchanged over time.

Selection bias was also a potential limitation of this study. Though consideration of this potential problem was addressed in study design (by enrolling all patients who met study inclusion criteria and agreed to participate), patients who chose to participate may have had different characteristics from those who refused. However, the vast majority (96%) of patients approached agreed to participate and those who did not choose to participate were similar in age and gender distribution.

The main purpose of this study was to quantify the amount of functional return following injection treatment in older adults. Significant functional return was observed at one month and approached significance at three months. The second purpose was to explore baseline patient characteristics that may have influenced response to treatment. Baseline emotional health emerged as a significant patient characteristic at both follow-up periods. This association is supported by previous related research and should be included in future studies examining the effectiveness of injections in older adults. If low baseline emotional status is a risk factor for poor response to treatment, physicians may choose to evaluate the emotional health of their older patients before treatment begins.

CHAPTER 4

The association between injection treatment and back pain caused by lumbar spinal stenosis in older adults

INTRODUCTION

Lower back pain is one of the most common health-related complaints in the adult population. Thirty percent of Americans 65 years and older reported symptoms of lower back pain in 2004 [1]. With an aging population, the proportion of people over the age of 65 is expected to reach 20% by the year 2030. Because of this increase in older adults, lumbar spinal stenosis associated with arthritic changes will also likely increase. In older adults, lower back pain is most often caused by degenerative lumbar spinal stenosis. Stenosis is the narrowing of the spinal canal, causing pressure on the nerve roots and is frequently treated surgically. Lumbar spinal stenosis is one of the most common reasons for back surgery in patients 65 years and older [2]. However, risks associated with surgery increase with age [3-5] and older patients may choose non-surgical treatment for their lower back pain, including injection treatment.

Injection treatment, usually consisting of anti-inflammatory medications and analgesics, has improved since the mid-1990's when fluoroscopic guidance was developed [6]. Information about injection treatment for lower back pain is limited, especially in the older population. An extensive review of published literature regarding injection treatment revealed a paucity of information about older adults diagnosed with lumbar spinal stenosis [6-13]. In this study, pain relief following injection treatment has been examined in patients over age 60, diagnosed with lumbar spinal stenosis primarily caused by degenerative changes. Variations in pain relief according to patient attributes were also assessed. To our knowledge, such results have not been reported in the literature.

METHODS

Patient Population

All patients ≥ 60 years old, who had been diagnosed with lumbar spinal stenosis and were scheduled to receive any lumbar injection for lower back pain at the Spine Center were eligible for review. Diagnosis of LSS was confirmed using Magnetic Resonance Imaging reports and clinical notes. Potential study patients were identified by reviewing Injection Room schedules two weeks in advance. Exclusion criteria were receipt of a previous injection in the lumbar region within the past 6 months; lumbar surgery within the past two years; history of lumbar fracture; acute disc herniation; malignancy or infection; inability to provide informed consent due to dementia or cognitive impairment; co-existing musculoskeletal conditions that would negate functional improvement with injection (e.g., severe Parkinson disease, or hemiparesis) or amputation of any lower extremity. All patients who agreed to participate provided signed consent forms and completed one general health questionnaire and one questionnaire specific to back pain before their scheduled injections. Eighty-nine patients were approached to participate in the study and 86 (96%) agreed and completed baseline questionnaires.

Approximately three weeks following baseline injection, patients were mailed one-month follow-up questionnaires. If the questionnaires were not returned within 2 weeks, the participants were contacted by phone. Two additional calls were made if the surveys were still not returned. The process was repeated for the three month follow-up period.

Treatment

Epidural Steroid Injection Procedure:

Patients of two physiatrists were included in the study. One physiatrist administered injections to 93.5% of patients (n=58). In the procedure room, the patient was placed in a prone position. The skin over the intended interlaminar target site was marked and prepped in the usual sterile fashion. The skin and subcutaneous tissue were anesthetized with 1% lidocaine mixed with sodium bicarbonate 8.4% (10:1). The tip of a 20-gauge, 3.5-inch Tuohy spinal needle was advanced under intermittent fluoroscopic guidance towards the target. Loss of resistance with air was used to identify the epidural space. After negative aspiration for blood and cerebrospinal fluid, Isovue was injected to confirm epidural placement. Subsequently, 5 mL of injectate (1 mL Triamcinolone Acetonide (40 mg/mL) and 4 mL 0.5% preservative-free Xylocaine) was administered. The needle was removed. (For multiple levels, 5 mL of injectate was distributed equally between levels injected. For caudal injections, 10mL of injectate (1 mL Triamcinolone Acetonide (40 mg/mL), 5 mL preservative-free normal saline, and 4 mL preservative-free 0.5% Xylocaine) was slowly administered without resistance).

Outcome Measure

SF-36

The primary outcome measure used for this study was the paper and pencil version of the Short Form-36 (SF-36 version 2) [31]. The SF-36 Questionnaire is a multi-purpose 36-item questionnaire used to assess functional health and well-being of adults. It is one of the most

frequently used questionnaires to assess health related quality of life in patients with back pain [25] and has been used in large-scale studies examining musculoskeletal issues, including a prospective study by Zanoli examining 451 patients with degenerative lumbar spine disorders [25]. The SF-36 was also used by Vogt et al., in the evaluation of 5,995 men 65 years and older in the Osteoporotic Fractures in Men Study [28].

The questionnaire represents multiple indicators of health including eight components. Four of these components relate to physical health and produce the measure *Physical Component Summary* (PCS). The remaining four components relate to mental health and produce the *Mental Component Summary* (MCS). In this study, two components were used; the Pain sub-score of the PCS (as a primary outcome for long-term pain) and the MCS (as a covariate).

The SF-36 surveys were scored using Quality Metrics SF-36 scoring software by a research assistant. Training to use the scoring software was given by the orthopedics department research coordinator. All survey scores were manually entered into an ACCESS database form by the research assistant and every fifth record was checked for accuracy by the primary investigator.

Covariates Measured

To assess physical attributes that could affect the response to treatment for pain and function, information about gender, age, body mass index (BMI), hip or knee replacement surgery history and co-morbidities was collected. Co-morbidities were scored using the Charlson Comorbidity Index (CCI) [30]. The CCI includes 19 co-morbidities, selected based on their association with mortality. It includes conditions related to cancer, diabetes, heart disease,

liver disease, renal disease, chronic pulmonary disease and others. Following retrieval of diagnosis histories using electronic medical files, medical conditions relevant to Charlson Index were recorded and the Index was computed by the first author. Results were verified by a dedicated orthopedic research resident. Medical records were also used to collect information on patient history of hip or knee replacement surgery to adjust for other lower extremity arthritic changes common in this age group and were included in the analysis.

Magnetic Resonance Imaging reports were reviewed for information about lumbar spinal stenosis diagnosis. Reports that indicated acute disc herniation in the lumbar region as being the primary diagnosis were not included in the study. When available, images were reviewed to determine LSS severity. A mid sagittal diameter of ≥ 13 was classified as "mild", 11 to 12 was classified as "moderate" and ≤ 11 was classified as "severe [32, 33].

To adjust for other pain control medications that may interfere with injection treatment, information about narcotic use was also collected. Medication lists were reviewed using electronic records and noted as "yes" or "no" regardless of dosage of medications. Narcotic use was defined as being used or reported within three months of baseline injection.

To adjust for other lower extremity joint arthritis common in this age group, information was collected on history of total hip or knee replacement surgery using medical records. Demographic and anthropometric information was collected using hospital administrative data and medical records. Information was also collected on body mass index (BMI) and demographic variables (gender, age and race). Information about race was not consistently reported in patient files and was not included in the analysis.

Data Collection

Demographic information was collected using hospital administrative data and medical records. Survey scoring was accomplished using Quality Metrics scoring software for the SF-36 survey. A standard was created and a corresponding data management program was developed using Microsoft ACCESS [24]. Data collected on paper forms were entered by a trained research assistant and the first author. Quality of data entry was verified by reviewing every fifth record. ACCESS files were then exported using StataTransfer. All statistical analyses were completed using Intercooled STATA SE 9.0 [21].

Analytic Plan

Descriptive statistics summarize patient characteristics such as gender, baseline emotional status (MCS), BMI, co-morbidities, narcotic use and history of total hip or knee replacement surgery (THKR). See Table 1. Baseline MCS and BMI were transformed to categorical variables. For categorical variables (gender, baseline MCS, BMI, co-morbidities, narcotics and THKR), numbers and percentages were presented. Age was presented as a continuous variable with mean, standard deviation and range. T-tests compared physical function between baseline and one month and between baseline and three months for each patient characteristic category (i.e. gender, age 60-69, age 70+, etc.). See Table 2. Differences in Pain score changes among patient categories (i.e. BMI groups) were assessed using analysis of variance tests. Significant variables in the univariate analysis were entered into a multiple regression model. Change in pain was examined in a series of linear mixed effects models. The mixed effects model assumes that repeated measurements in the same individual are not independent and allows individuals to have unequal numbers of observations. In this study, the

outcome measure included function at baseline, 1 month and 3 months and the covariates included MCS,BMI, gender, age and co-morbidities). The outcome measure was collected at three timepoints, and some of both outcome data and covariate information were missing. The fixed effects portion of the model consisted of the variables that were significant in the univariate analysis (analysis of variance). Patient level intercepts were modeled as random effects. This term accounts for between-subject variation. For example, in this study, baseline measurements of pain were analyzed as separate values for each patient, rather than as a mean. Unconditional models (fixed time) and conditional models (fixed time, BMI, MCS, age, gender) were compared to determine changes in variance after the addition of variables to the model. Akaike's information criterion was used to assess goodness-of-fit between the models.

All variables in the analysis were also tested for an interaction with time (age, gender, baseline emotional health, BMI, co-morbidities, narcotic use, hip or knee replacement). Likelihood ratio tests were used to compare models with and without time/variable interactions. Test results producing significant p-values ($p<.05$) indicated time interactions were present and were included in the final model. By adding variables into the model individually, potential interactions between variables were also evaluated and significant interactions were included in the final model. Model assumptions of linearity, normality, independence of errors, and homoscedasticity of errors were examined graphically and analytically and were adequately met. ACCESS files were exported using StataTransfer [19] for statistical analyses using Intercooled STATA 9.0 [19]. All available data from all participants were used, as long as at least one follow-up survey was returned.

RESULTS

Eighty-six patients were initially enrolled and completed baseline SF-36 questionnaires administered by the first author from January 1, 2008 to July 1, 2008. All patients signed study consent forms approved by the IRB. Participants were followed at one month and at three months following baseline injection (Figure 1). At one month, 4 participants withdrew from the study, 2 were dropped from the study (for having a second injection before follow-up (n=1) or for never having the first injection (n=1), 4 did not return the first follow-up surveys, 7 received nerve blocks, 6 received radiofrequency denervation and 1 died. Of the initial 86 participants, 62 were still enrolled after one month and 62 returned SF-36 surveys. At three months, 1 withdrew from the study and 4 did not return the second follow-up surveys. At the end of the second follow-up period, 61 participants were still enrolled and 56 returned three-month surveys. All patients remaining in the study received epidural steroid injections.

Patient characteristics including gender, emotional status (MCS), BMI, co-morbidities, narcotic use and history of total hip or knee replacement surgery (THKR) are summarized and presented in Table 1. The mean age of participants was 74 (SD=8.1, range 60 to 90), 68% were female, 60% had high emotional health (MCS≥50) and 44% were obese to morbidly obese (BMI≥50). Baseline scores differed significantly by patient characteristics including baseline emotional health and body mass index.

Figure 4.1: Patient enrollment.

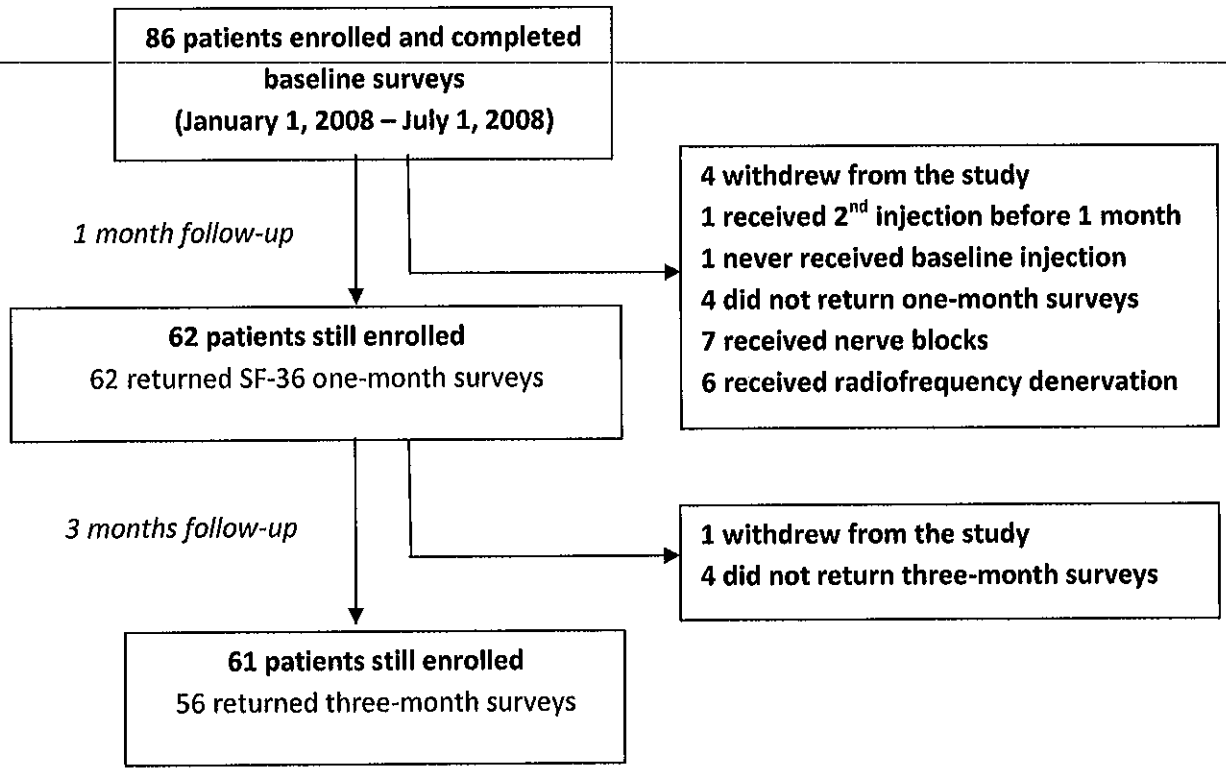
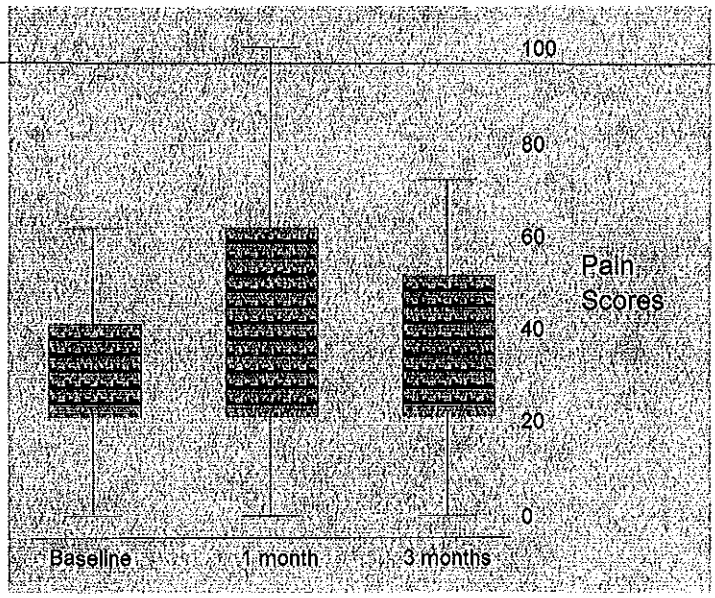


Table 4.1: Patient characteristics at baseline

Characteristic	N	%	SF-36 Pain Score Baseline Mean (SD)
Total	65	100	27.4 (1.7)
Age			-
Mean	74		
SD	8.1		
Range	60-90		
Gender			
Male	21	32	28.8 (14.2)
Female	44	68	26.7 (13.3)
SF-36/MCS *			
Low (< 50)	26	40	21.3 (10.5)
High (≥50)	39	60	31.4 (13.9)
Body Mass Index			
Normal Weight (<25)	14	21	28.5 (13.2)
Overweight (25-30)	17	26	26.4 (14.0)
Obese (30-34.9)	12	18	30.8 (16.4)
Morbidly Obese (>35)	12	18	27.6 (7.7)
Comorbidities *			
0	31	48	28.0 (14.7)
1	10	15	22.3 (12.3)
2	11	17	30.7 (13.4)
≥3	13	20	26.9 (11.9)
Narcotic Use *			
Yes	16	25	22.1 (12.6)
No	38	58	29.4 (14.1)
Hip or Knee Replacement			
Yes	11	17	30.2 (15.8)
No	43	66	26.5 (13.6)

Note: Mean SF-36 Pain score for the general population = 75.2 (SD=23.7) [34]
Baseline scores between group categories compared: * $p<.05$ (t-test); ** $p<.05$ (chi-square)

Figure 4.2: Mean Pain scores at baseline, 1 month and 3 months



Changes in SF-36 Pain scores at one and three months were tabulated overall and by patient characteristics in Table 2. Overall, significant improvement was found at both one month and three months follow-up. SF-36 Pain scores showed a 14.1 ($p<.05$; 95% CI: 9.5, 18.7) point reduction in pain at one month and an 8.3 ($p<.05$; 95% CI:4.0, 12.6) point reduction in pain at three months. Significant differences ($p<.05$) in Pain score changes from baseline to one month were found between BMI and emotional status categories. Baseline, one month and three month means of Pain scores are presented in Figure 2.

Results from a linear mixed effects model analysis are presented in Table 3. Variables found to have significantly different Pain score changes at either one or three months were included in the analysis (BMI and MCS) as well as gender and age. No variable interactions or interactions with time were found or included. To account for small sample size, body mass index categories were collapsed to two categories, obese ($BMI<30kg/m^2$) and non-obese ($BMI\geq30kg/m^2$). Comparison of covariance estimates of the conditional model showed a modest improvement in goodness of fit (0.69%, 0.93%, 0.79% and 0.64% of additional variance

explained for emotional health, BMI, age and gender; p-value<.05) when compared to the unconditional model (time alone).

The only variables showing significance were baseline emotional health and body mass index. Pain scores were significantly improved for patients with high baseline emotional health and for patients who were obese. In patients with high baseline emotional health, Pain scores improved by 14.1 (p<.05; 95%CI 6.9, 21.3) points over three months, as compared to patients with low baseline emotional health. In patients who were obese, Pain scores improved by 7.9 (p<.05: 95% CI; 1.0, 14.8) points over three months, as compared to patients who were non-obese. Mean Pain scores at baseline, one month and three months by emotional health status and by BMI status are presented in Figures 3 and 4.

Table 4.2: Change in SF-36 Pain scores from baseline to one month and baseline to three months.

Patient characteristics	SF-36 Pain change Baseline to 1 month mean (SD) N=61	p	SF-36 Pain change Baseline to 3 months mean (SD) N=56	p
Total (n)	14.1 (9.5, 18.7)	<.05	8.3 (4.0, 12.6)	<.05
Gender				
Male	10.9 (2.7, 19.0)	<.05	9.4 (4.0, 14.7)	<.05
Female	15.4 (9.7, 21.1)	<.05	7.7 (1.8, 13.7)	<.05
Age				
60-70	16.2 (7.7, 24.7)	<.05	7.6 (-0.12, 15.3)	<.05
>70	12.8 (7.2, 18.3)	<.05	8.7 (3.4, 14.0)	<.05
Emotional Status (SF-36/MCS)		**		
< 50	9.5 (3.9, 15.0)	<.05	8.1 (3.5, 12.7)	<.05
≥ 50	17.3 (10.5, 24.1)	<.05	8.4 (2.0, 14.8)	<.05
Body Mass Index		*		
Normal Weight (<25)	15.3 (7.6, 23.0)	<.05	3.9 (-6.6, 14.4)	0.44
Overweight (25-30)	1.4 (-5.3, 8.2)	0.66	6.7 (-0.68, 14.1)	0.07
Obese (30-34.9)	19.6 (7.1, 32.1)	<.05	7.9 (-5.2, 21.0)	0.21
Morbidly Obese (>35)	19.9 (1.32, 38.5)	<.05	14.8 (7.0, 22.5)	<.05
Narcotics				
Yes	14.8 (5.9, 23.7)	<.05	10.7 (3.6, 17.7)	<.05
No	13.2 (7.4, 18.9)	<.05	6.7 (0.43, 13.0)	<.05
Co-morbidities				*
0	10.9 (5.3, 16.5)	<.05	7.0 (1.3, 12.7)	<.05
1	18.2 (3.7, 32.7)	<.05	17.9 (6.4, 29.4)	<.05
2	15.5 (2.4, 28.6)	<.05	-1.2 (-12.9, 10.5)	0.82
≥3	17.2(2.8, 31.5)	<.05	11.2 (0.23, 22.1)	<.05
Hip or Knee Replacement				
Yes	11.0 (-4.9, 26.8)	0.16	3.9 (-6.8, 14.5)	0.43
No	14.4 (9.8, 19.0)	<.05	9.1 (3.6, 14.5)	<.05

P-values represent t-test results comparing baseline and follow-up scores;

1 month change in pain = 1 month SF-36 Pain - baseline SF-36 Pain;

3 months change in pain = 3 months SF-36 Pain - baseline SF-36 Pain;

* One way ANOVA p-values ≤ .05; **One way ANOVA p-values ≤ .10. Compared variable categories (i.e. male v. female)

Table 4.3: Predictors of change in pain over 3 months (multiple regression)

Patient characteristics	SF-36 Pain change β (95%CI)
BMI (obese vs. non-obese)	7.9 (1.0, 14.8) *
MCS baseline (<50 vs. ≥50)	14.1 (6.9, 21.3) *
Age (60-69, vs. 70+)	0.25 (-6.7, 7.2)
Gender (male vs. female)	-0.39 (-8.2, 7.4)

Based on linear mixed effects model analysis; * $p<.05$;

Figure 4.3: Mean Pain scores at baseline, 1 month and 3 months by emotional health status.

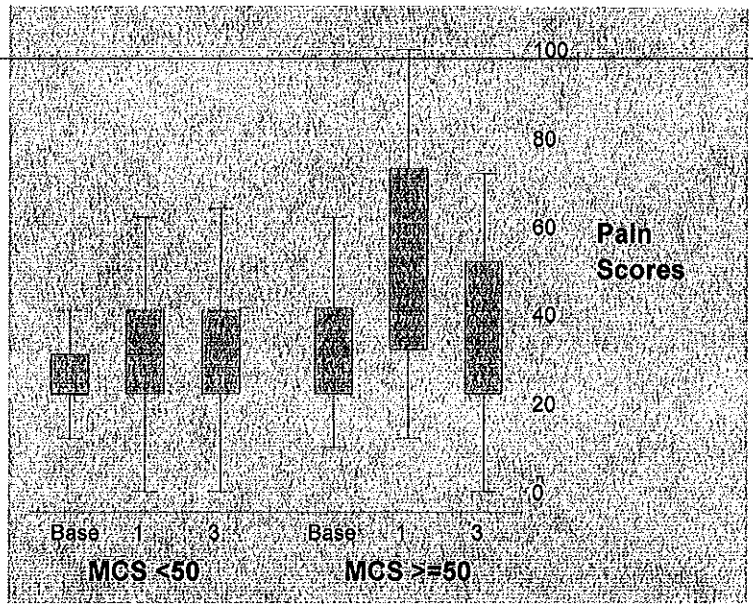
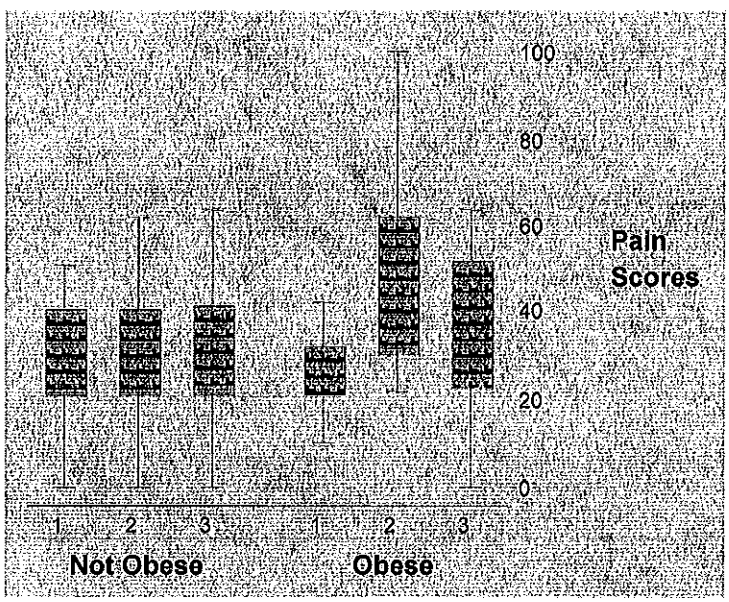


Figure 4.4: Mean Pain scores at baseline, 1 month and 3 months by body mass index.



DISCUSSION

This study provides new information about injection effectiveness in the older adult population. Despite the fact that lumbar spinal stenosis occurs more frequently in aging adults [14] and affects 5 of every 1,000 Americans over age 50 [15], the effectiveness of injection treatment is understudied. This study provides much needed quantitative information on the effectiveness on pain relief of injection therapy using steroids and analgesics.

There were three main findings of this study. First, significant pain relief was observed in older adults for up to three months after injection treatment. Second, patients with high emotional status experienced more pain relief than patients with low emotional status. Third, pain relief varied by body mass index.

Body mass index has been associated with comorbidities, including osteoarthritis and back pain, in previous literature [35]. Obesity has also been associated with higher fatigue and less activity, especially in patients with knee osteoarthritis [36]. In this study, patients who were obese to morbidly obese experienced more pain relief than lighter patients. Variations in response to pain treatment could be associated with lower activity levels in obese patients, resulting in less pain. The effects of injections could also have been less effective in patients with a history of hip or knee arthritis, as noted in an earlier study by Bischoff-Ferrari [37]. There are two possible explanations for this response: First, arthritis may be more advanced in these patients than in patients who have not had hip or knee surgery, which may have affected their response to injection medications. Second, referred hip and/or knee pain may confound pain relief due to local treatment of the lumbar stenosis. Inconsistent results found in these groups could also be due to the size of the sample, especially when distributed among sub-categories.

High emotional status was found to be strongly associated with greater improvement in pain at one month. This finding parallels findings in previous studies examining other musculoskeletal disorders, including total knee replacement [38] and total hip replacement [37]. However, this is the first study on older patients diagnosed with lumbar spinal stenosis to produce these results. It is important to note that patients with low emotional health had more pain at baseline (PCS=21.3) compared to patients with high emotional health (31.4). Thus, it is not clear if greater pain preceded the lower emotional health or vice versa. This will provide clinicians with valuable information when screening their patients at baseline. If emotional status has impact on how well patients respond to injection treatment, clinicians may discuss this association with patients. This change may maximize the benefit of injection treatment in this sub-population of aging patients.

A limitation of this study was that the effects of lumbar spinal stenosis severity could not be determined. Stenosis severity has been documented in previous studies using Magnetic Resonance Imaging (MRI) films for measurement [13, 32, 33]. In this study, only a minority of original MRI films were available to the study team for review and severity information could not be consistently collected. However, MRI reports were available and reviewed to confirm diagnosis. Reports that indicated disc related LSS as being the primary diagnosis were not included in the study. Future research projects examining injection treatment for lumbar spinal stenosis should determine image availability before data collection begins.

A second limitation was the study size. Enrollment of study participants was limited to one location over a relatively short period of time (6 months). The inclusion of patients from only one study center may affect the generalizability of the response to treatment found in this cohort. However, this was the first study to examine the results of injection treatment in older

adults with a diagnosis of LSS specifically caused by degenerative changes. In addition, the study site was a clinic specifically designed to treat patients with back pain, serving a diverse population in a large metropolitan city in the northeast. As the only spine center in the area, the patient population is representative of the surrounding area. These results may be used in the design of future, multicenter studies.

A third limitation of this study included a lack of sufficient power to determine the differences in treatment effects within these sub-categories (BMI and emotional health), making it impossible to make recommendations according to specific conditions of the potential patients. Future research should increase sample size to adequately examine the relationship between patient characteristics and injection effectiveness, especially in regard to emotional health status as a potential predictor of outcome.

Study design may also be considered a limitation. Ideally, a comparison group would have provided the best information in determining injection treatment effectiveness in this cohort. However, a randomized control design poses problems with invasive procedures such as injection treatment. Many clinicians recommend injection treatment for lower back pain as a last resort before surgery. Randomizing patients to either surgery or injection treatment may likely cause some ethical considerations in study design. Selection bias was also a potential limitation of this study. Though consideration of this potential problem was addressed in study design (by enrolling all patients who met study inclusion criteria and agreed to participate), patients who chose to participate may have had different characteristics from those who refused. However, patients who agreed to participate were compared to patients who did not agree, and had similar characteristics (age, gender).

Additional information about other patient characteristics such as socioeconomic status and lifestyle may have also been useful in assessing differences in response to injection treatment. However, in this study, patient surveys were completed within a short period of time before entering the injection room and time was limited. Future studies may benefit from collecting this information at a less sensitive time.

In general, pain scores improved substantially one month after treatment. Three months after treatment, an improvement was seen as well, but not as strong as at one month. Clearly, pain medications administered by injection did not have a lasting effect, but were still providing some pain relief even after three months. Though this amount of pain relief will be satisfactory for some patients, others may prefer a longer effect and may prefer surgery to injection treatment. However, this information will be useful for clinicians who consider offering injections as an option for their aging patients.

The results of this study suggest that injection treatment may reduce lower back pain in older patients with lumbar spinal stenosis for up to three months or more. Treatment effects may vary by patient characteristics which should be considered when referring patients to injection treatments. To further examine potential predictors of achieving maximum pain relief, future research should increase sample size. An important finding of this study was that good baseline emotional health demonstrated a strong association with pain level following injection treatment. Future research should take this important relationship into account in study design.

CHAPTER 5

Conclusion

Following a thorough search through clinical literature, several gaps were found about the effectiveness of injection treatment in older adults. Only seven studies were located that specifically examined older adults with lumbar spinal stenosis primarily caused by arthritic changes. The goal of this project was to address the strengths and limitations of those studies, by designing and carrying out a new study based on that information.

After careful review, it was determined there were several inconsistencies in past study designs.

The first problem concerned the measurement of the outcome following injection treatment. The primary concern for this treatment was to decrease or eliminate pain associated with lumbar spinal stenosis. However, the majority of studies identified in the literature review used a simple Visual Analogue Scale (VAS) or Numeric Pain Scale to obtain this measurement (n=5). This was an important consideration in the design of our studies. As the Short Form 36 (SF-36) is an established survey tool that has been extensively validated in a number of populations, including degenerative arthritis and back pain, the Pain subscale score was deemed to be a more than sufficient tool for assessing pain. VAS measurements are a standard screening tool in many clinic settings, and were used in the design of our retrospective study simply because they were available. However, in the design of our prospective study, the SF-36 Pain subscale was used to obtain a more accurate measurement of pain.

The second concern for injection treatment was to increase function. Though this is generally a secondary consideration following pain relief, function was also assessed using a variety of methods, including the Roland Morris Disability Questionnaire, the Oswestry

Disability Index (ODI) and walking tests. Since the ODI was designed to measure function in patients with spinal disorders and has been reported as the "gold standard" for evaluating function in patients with lower back pain [29], this survey tool was used in our prospective study as well. The ODI served as a measurement of spine-specific function, and was also chosen to better serve orthopedic audiences. To provide a general health measurement of function, the Physical Component Score (PCS) of the SF-36 was used. It has also been recognized in SF-36 survey guidelines [39] that additional surveys may be administered along with the SF-36 and recommended that the SF-36 be placed before the second survey. These guidelines were followed in our procedures for the prospective study.

Follow-up periods were also found to be varied in the previously reviewed articles. For this reason, our retrospective study was a useful tool in determining what follow-up periods would be reasonable and useful in the design of our prospective study design. The retrospective study examined the rate and timing of second injections received by patients following their initial injection. It was found that patients returned for second injections after approximately 3.7 months and that 57% of patients returned for injections within six months. Because of the retrospective study design, the reasons for returning (or not returning) for a second injection were not known. However, the results did show that the majority of patients desired to have a second injection between three and six months (presumably, because their pain had returned). Therefore, it was a reasonable conclusion to collect information on pain and function at three months as a long term measurement, and at one month as a short term measurement. Indeed, the results of both the pain and function studies did show marked improvements at one month, and declining effects at three months, as expected.

The second problem concerned the methods used for diagnosis of lumbar spinal stenosis (LSS). Some studies used Magnetic Resonance Imaging (MRI), some used symptoms alone and some used both. These methods for determining diagnosis were also important in assessing severity of LSS. In addition, both the retrospective and prospective studies included only patients diagnosed with LSS caused by degenerative changes or osteoarthritis (not disc displacement). The review of MRI reports were important tools for both diagnosis and severity. First, diagnosis was confirmed by MRI reports and clinical notes by the attending physiatrist. In previous studies, diagnosis has been determined by both imaging and symptoms. However, since MRI has been used most consistently, it was deemed to be the most accurate measurement available, especially when confirmed with clinical notes about symptoms. Second, severity was determined by measurements performed on the available images by a research orthopedic resident. Studies published after the prospective study had begun used these techniques and thus were incorporated into the study design. However, it was discovered that approximately 75% of images were not available for viewing, and this variable was subsequently dropped from the analysis. This discovery was an important lesson in the process of the study, as recommendations for future similar studies will include confirming the presence of MRI before data collection begins.

The third problem concerned the inclusion of a wide variety of age ranges in previous studies. Though older patients were included in previous studies, they were not stratified in the analyses and it was not possible to draw any conclusions based on age alone. The focus of our studies was to gain more information about injection treatment in older people. Thus, both the retrospective and prospective studies were limited to only patients aged 60 and over.

Recommendations for future research included a focus on older people, as well as including specific information about pain, function, complications and co-morbidities. Both the retrospective and prospective studies focused specifically on older adults. The retrospective study was designed to gather information about the use of injections in this age group and to learn more about their characteristics (i.e. gender, age, BMI). The prospective studies were designed to build on that information by determining follow-up periods as well as patient characteristics that may be important in treatment response. The prospective studies clearly defined pain and function by using established surveys in musculoskeletal research. Co-morbidities were also assessed using a well established tool, the Charlson Comorbidity Index [30]. Though this index was designed to collect information about a wide variety of diseases and conditions, a more refined profile about study patients may have been more useful. However, it was not within the scope of this project to use a more specific tool. Future research may include the use of a more detailed instrument. Complications were not collected in either the retrospective or prospective studies. Information about complications in previous literature is limited, but those that have been reported were minimal. Therefore, follow-up information was limited to the surveys used for pain and function assessment only.

Another recommendation involved the potential use of randomized control designs to further investigate the effectiveness of injection treatment. One study included in the literature review used this study design [12]. However, this study was not completed in the United States and may not have been subjected to the same guidelines of our Institutional Review Board. There would likely be ethical considerations with an invasive treatment such as spine injections, and this design may be problematic in our institution and others.

The results of both the retrospective and prospective studies showed several important conclusions. First, the majority of patients over age 60 returned for a second injection within six months of the first injection, and most returned just before four months. Second, patients over age 70 did not return as soon as younger patients (aged 60 to 69). Third, patients experienced a significant reduction in pain after one month, but pain relief was not as effective after three months. Fourth, patients experienced a significant increase in function after one month, but there was some decrease in function by three months. Fifth, good emotional health was associated with more pain relief and better function over three months following treatment. These findings will be important in the design and implementation of future studies examining injection treatment in older adults. Based on these results, recommendations for future research include; a larger, multicenter study; verification of MRI reports and images; a more extensive co-morbidity index designed to cover a wider range of diseases and conditions; and, emotional health screening and measurement (possibly including a more in depth tool in place of the SF-36 MCS). With a more detailed and focused design, physicians and older adult patients will have more information to make decisions about treatment for their lower back pain.

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