



## Musculoskeletal Clinical Regulatory Advisers, LLC

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# Advancements in Orthopedics

## Non-Surgical Treatment Options Can Address Chronic Pain Due to Lumbar Spinal Stenosis

### INTRODUCTION

Lumbar spinal stenosis, or the narrowing of the neural canal, is a degenerative condition affecting millions of Americans. Many patients with this condition are asymptomatic, particularly earlier in life, but many others, particularly those age 50-70, experience painful symptoms that require examination and treatment. Physicians have a variety of treatment options available to treat chronic pain associated with spinal stenosis.

This article examines available non-surgical (conservative care) treatment options.

### CONSERVATIVE CARE TREATMENT OPTIONS

In treating chronic pain associated with lumbar spinal stenosis, physicians almost always begin with conservative care or non-surgical options.<sup>1</sup> Examples of non-surgical treatment options include the following:



**Physical Therapy**—Physical therapy commonly is prescribed for patients experiencing back pain. Often, the goal of physical therapy is to strengthen the supportive musculature to take pressure away from the spine while limiting painful arcs of motion. Physical therapy may include heat or cold therapy, electric stimulation, traction, stretching exercises, or posture training<sup>2</sup> and may last several sessions or several months.

**Exercise**—Exercise is an important component of any treatment regimen for spinal stenosis.<sup>3</sup> While exercise is not curative, range-of-motion and other exercises can help reduce painful symptoms associated with anatomical degenerative changes.

**Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)**—NSAIDS often are used to reduce inflammation or swelling associated with lumbar spinal stenosis. While these products can be effective in reducing nominal pain, patient use should be monitored by a physician due to potential adverse events associated with their prolonged use.<sup>4</sup>

**Epidural Injections**—Epidural injection allows anti-inflammatory medications (cortisone) to enter the epidural space of the neural canal in an effort to reduce inflammation of the nerve roots that may be causing a patient's back and leg pain. Patients may receive one or more injections, depending upon response. Pain relief can be significant but usually is temporary.

### CONCLUSION

Many patients find pain relief for symptoms associated with lumbar spinal stenosis through conservative care therapies. However, these treatments often are palliative in nature rather than curative. In its treatment guidelines for lumbar spinal stenosis, the North American Spine Association (NASS) notes that

conservative care treatment options do not treat the general narrowing of the neural canal.<sup>5</sup>

For many patients, successful treatment using conservative care options may delay the need for surgical repair. Regardless of the circumstance, at such point as conservative care options cannot adequately relieve pain symptoms, surgical treatment should be considered.

### IMPORTANT INFORMATION FOR CONSIDERATION

- Conservative care typically is the first line for treating chronic pain
- Many conservative care treatment options exist
- Conservative care is intended to treat the symptoms of lumbar spinal stenosis, not the condition itself
- When conservative care does not adequately relieve pain symptoms, surgical intervention to treat the condition may be required

# Understanding Comparative Effectiveness and its Potential Uses is Key to Defining its Success

## INTRODUCTION

The rapid rise in national health care expenditures in recent decades has prompted considerable discussion among policymakers and stakeholders regarding ways to encourage more prudent purchasing of health services. Among the many proposals for curbing spending is the development of a Comparative Effectiveness Institute that will compare competing technologies and procedures to provide patients, providers, and other stakeholders with the information needed to make good treatment choices. It is believed that better information will lead to more effective care and fewer resources spent on care that does not improve patient outcomes.

## WHAT IS COMPARATIVE EFFECTIVENESS?

The Congressional Budget Office provides an excellent and succinct definition of comparative effectiveness<sup>6</sup>:

“As applied in the health care sector, analysis of comparative effectiveness is simply a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risk of each option, or it may also weigh both the costs and the benefits of those options.”

Congressional Budget Office  
Research on the Comparative Effectiveness of Medical Treatments

Comparative effectiveness is different from technology assessment or technology evaluation because it compares evidence supporting available treatment options for a particular condition, allowing users more information when deciding which treatment is likely to be more effective for a particular patient.

## WHAT ENTITY WOULD PERFORM THESE ASSESSMENTS?

Currently, Members of Congress and the Obama Administration have signaled interest in creating a Comparative Effectiveness Institute. Additionally, the Congressional Budget Office, the Medicare Payment Advisory Commission (MedPAC), and other independent stakeholders have evaluated this issue. Current recommendations and blueprints envision an independent center funded through a combination of public and private contributions.<sup>7</sup>

## WHAT INFORMATION MAY BE COMPARED?

If established, an independent comparative effectiveness institute may review the following:

- Literature reviews
- Meta analyses
- Claims analyses
- Economic and cost-effectiveness studies

Additionally, the entity may also perform selected prospective analyses, including the following:

- Clinical trials
- Management of registries
- Cohort studies

Most stakeholders appear to agree that comparative effectiveness can provide important information regarding the benefits of available treatments that can be used in determining the most appropriate treatment for a particular patient. Stakeholders disagree, however, regarding the role of cost or value data in comparative effectiveness evaluations performed by an entity.

## HOW WILL PAYORS USE COMPARATIVE EFFECTIVENESS EVALUATIONS?

The intended outcome of comparative effectiveness research, whether performed by a new independent entity or by an existing agency (such as the Agency for Health Research and Quality), is to provide better information regarding treatment choices. While it is important for patients and providers to have the best information possible regarding treatment options, it is equally important to understand how health care payors, both public and private, will use this same information in the administration of health plans and programs. The extent to which health plans, either collectively or individually, can educate stakeholders regarding the potential use of these analyses in coverage decision making for new and existing technologies will significantly impact this program's success.

# Article Review: Evaluating the Evidence: Is There a Rigid Hierarchy?

Ho, Peterson and Masoudi  
*Circulation* 2008; 118; 1675-1684

In this issue of *Advancements in Orthopedics*, we review an article published in the *Journal of the American Heart Association* that provides an excellent summary of the hierarchy of evidence, forms of clinical study and the usefulness of research in addressing questions of safety, efficacy and effectiveness. Ho and his colleagues describe the common pyramid of evidence, as well as the utility of randomized controlled clinical trials (RCTs), cohort studies and case series. The authors conclude that while RCTs are valuable in evaluating efficacy, "...experimental studies are not always feasible or appropriate and are often not well suited to answer important questions, such as those on the safety and effectiveness of therapies in real-world populations, the impact of risk factors on outcomes, or the effect of policy interventions." Ultimately, the authors conclude, a valid interpretation of the literature requires a good understanding of the strengths and limitations of different study designs, and an appreciation of the circumstances in which the traditional evidentiary hierarchy does not apply.

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Evaluating the Evidence:  
Is There a Rigid Hierarchy?  
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"Evaluating the Evidence: Is There a Rigid Hierarchy?" is an excellent article that provides brief descriptions about the use of published evidence in the decision-making process. Authors provide good descriptions about each of the major components found within experimental and observational studies. With regard to the use of a non-inferiority study design, Ho, Peterson and Masoudi remind the reader that the existence of an established, efficacious therapy precludes the use of a placebo-controlled study on ethical grounds, and that the established clinical therapy must be used as a comparator.

In summary, this published article may be used as a guide in the decision making process. As argued successfully by the authors, the cumulative body of evidence should be given great weight when deciding about the use and availability of alternative treatment options, with quality trial outcomes supplemented by alternative studies that address questions which could not feasibly have been answered in a randomized clinical trial.

## FOOTNOTES

- 1 Delamarter RB, Howard M.: Lumbar spinal stenosis. *Rehabilitation of the Spine, Science and Practice*. Editors Hochschular S, Cotler H, Guyer R, Chapter 37, pp. 443-456, Mosby, 1993.
- 2 Mayo Clinic, Spinal Stenosis Treatment. Available at: <http://www.mayoclinic.org/spinal-stenosis/treatment.html>
- 3 American Academy of Orthopedic Surgeons, Your Orthopedic Connection: Ask an Orthopedic Surgeon About Spinal Stenosis. Available at <http://orthoinfo.aaos.org/topic.cfm?topic=A00390>. Accessed January 5, 2009.
- 4 North American Spine Association Fact Sheet: *Lumbar Spinal Stenosis: What is It? How is It Treated?* Available at: <http://www.spine.org/Pages/ConsumerHealth/SpineConditionsAndTreatments/CommonProblemsCorrectiveActions/DegenerativeConditions/LumbarSpinalStenosis.aspx>
- 5 North American Spine Association Fact Sheet: *Lumbar Spinal Stenosis: What is It? How is It Treated?* Available at: <http://www.spine.org/Pages/ConsumerHealth/SpineConditionsAndTreatments/CommonProblemsCorrectiveActions/DegenerativeConditions/LumbarSpinalStenosis.aspx>
- 6 Congressional Budget Office Paper, *Research on the Comparative Effectiveness of Medical Treatments*, December 2007. Page 3.
- 7 More information on specific blueprints and proposals can be found in the following documents: MedPAC Report to Congress: *Reforming the Delivery System*. June 2008. Chapter 5: "Barack Obama and Joe Biden's Plan To Lower Health Care Costs and Ensure Affordable, Accessible Health Coverage For All," accessed December 5, 2008. Available at <http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf>

This newsletter and its contents are intended for informational use only. It is intended to highlight emerging technologies for musculoskeletal diseases. MCRA, LLC does not represent opinions of any health care provider and makes no representations regarding standard of care or how medical treatment should be administered.



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MCRA was founded in 2003 and provides "first-in-class" service to its clients through its superior knowledge base, global surgeon relationships and deeply experienced management team. MCRA places particular emphasis on working with companies at all stages of development, whether they are single-product companies or companies with several thousand technologies.



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