AAOS Clinical Guideline on Low Back Pain/Sciatica (Acute) (Phases I and II) Support Document

OVERVIEW

Goals & Rationale

This clinical guideline has been created to improve patient care by outlining the appropriate information gathering and decision making processes involved in managing low back pain with sciatica in adults. Musculoskeletal care is provided in many different settings by many different providers. This guideline has been created as an educational tool to guide qualified physicians through a series of diagnostic and treatment decisions in an effort to improve the quality and efficiency of care.

This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made by the treating physician following a full assessment of all circumstances presented by a patient, including the needs and resources of a particular locality or institution.

Scope & Organization

This guideline addresses the diagnosis and treatment of acute low back pain of uncertain origin in skeletally mature individuals, not associated with trauma, infection or major neurological deficit. Undifferentiated low back pain is extremely prevalent in the U.S. and its social and economic costs are great.

The Phase I guideline focuses on the four to six week period where this commonly occurring form of back pain will most likely improve or resolve spontaneously or will respond to various forms of activity modification, non-narcotic drugs and education. The guideline provides the user with information used during the initial assessment of the patient, through several critical exclusionary diagnoses and then on to the determination of a differential diagnosis. Once a differential diagnosis is reached, the user continues on to a flowchart specific to that diagnosis. Each diagnosis-specific flowchart guides the user through the initial treatment and possible modified treatment. The flowcharts end where referral to a musculoskeletal specialist is recommended. The Phase II guideline delineates a reasonable approach to further evaluation and treatment by the musculoskeletal specialist.

--Phase I (First Contact Physician)

The Phase I document represents the first stage of the guideline and is intended to address issues faced by **first contact physicians only** (including, but not limited to, family physicians, orthopaedic surgeons, rheumatologists) in the first

four to six weeks of evaluation and treatment. The skeletally mature patient presenting to any physician with acute low back pain should be evaluated to exclude the presence of the following critical exclusionary diagnoses: cauda equina syndrome, fracture, neoplasm, infection, progressive neurological deficit, chronic pain syndrome or persistent pain resulting from previous spinal surgery. The guideline provides the user with information on appropriate referrals if such diagnoses are made. After eliminating the previous conditions as sources of the patient's symptoms, the physician should proceed with approximately four weeks of some combination of activity modification, medication, self-applied thermal modalities and physical therapy according to the severity of symptoms. At four to six weeks a re-evaluation of the condition should occur along with possible referral to a musculoskeletal specialist.

--Phase II (Musculoskeletal Specialist)
On presentation to the musculoskeletal specialist, the patient is clinically re-evaluated for critical exclusionary diagnoses, previous treatment is evaluated and Phase I treatment may be repeated if deemed clinically appropriate. The patient's primary clinical diagnosis (A. Herniated Nucleus Pulposus/Herniated Lumbar Disc, B. Unremitting Low Back Pain/Instability, C. Spondylolysis, Lytic Spondylolisthesis, or Degenerative Spondylolisthesis/Stenosis or D. Lumbar Spinal Stenosis) then determines the treatment path subsequently followed. Non-surgical and surgical treatments are considered. Patient education and discussion of treatment options is an important component of the Phase II guidelines. The treatment goal of all Phase II guidelines is a return to active function and involvement in a back maintenance program.

Methodology
Revision panel: Thomas Haher, MD, Chairman; Andrew Merola, MD; Glenn Rechtine, MD; and William C. Watters, III, MD.
Panel: Original authors: David Wong, MD, Chairman; Thomas Errico, MD; Jeffrey Saal, MD; William Sims, MD; William C. Watters, III, MD, assisted by an advisory group consisting of Hansen Yuan, MD; Harry N. Herkowitz, MD; Elmer Nix, MD; Garth Russell, MD; Sam Weisel, MD; Reginald Cooper, MD; Don Long, MD; Jeffrey Susman, MD; Ernest Found, MD; and Gene Swanson, MD.

Process Overview: The Phase I Clinical Guideline on Low Back Pain was developed by a multi-specialty panel led by the American Academy of Orthopaedic Surgeons Task Force on Clinical Algorithms in cooperation with the AAOS Committee on Clinical Policies. Representatives from the AAOS Board of Councilors, American Association of Neurological Surgeons, the American College of Physical Medicine and Rehabilitation, the American Academy of Family Practice and North American Spine Society (NASS) participated in the panel. The Phase II Guideline was a cooperative project of AAOS and NASS using similar multi-specialty input. The panel, with the assistance of the AAOS and various private and academic medical centers, completed a review of the relevant literature, followed by a series of meetings in which information from the

literature was extracted and transformed into draft “decision trees.” Information from the literature was supplemented by the consensus opinion of the panel when necessary. The participating individuals then conducted multiple iterations of written review. Modifications, when supported by references from the literature were then incorporated by the panel chairman.

The revision panel, with the help of Value Health Sciences, performed a new literature search, reviewed and graded articles, completed an objective evaluation of the 1996 guideline, and incorporated information into the revised guideline as appropriate. Information from the literature was supplemented by consensus. The AAOS panel completed the update of the guideline with input from the North American Spine Society.

The revised guideline was reviewed and approved by various groups within the AAOS including the Evidence Analysis Work Group, Evidence-Based Practice Committee, Council on Research, Board of Councilors, and Board of Directors.

In developing and revising this guideline the original task force and the panel made every effort to be consistent with the American Medical Association’s Attribute of Practice Parameters. In brief, the guideline was developed by a physician’s organization with scientific and clinical expertise and it is based on a reliable methodology that integrates science and consensus. It is comprehensive and specific, is based on current information, and will be widely disseminated.

Literature Review: A search of MEDLINE was performed in order to update the literature used to develop the original guideline. English language journals were searched from 1988 to 2001; human studies of adults over 19 years of age were included. Of the abstracts generated by the search 341 articles were graded by the panel and included in the bibliography.

Weighing the Evidence: All literature cited in the bibliography was reviewed and evaluated for quality according to the following categories:

Type I	Meta-analysis of multiple, well-designed controlled studies; or high-power randomized, controlled clinical trial
Type II	Well-designed experimental study; or low-power randomized, controlled clinical trial
Type III	Well-designed, non-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series
Type IV	Well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies
Type V	Case reports and clinical examples

Consensus/opinion as it is used in bibliography: Articles representing expert consensus and not meeting the rigid I – V measurement are noted to represent consensus/opinion.

Consensus Development: The panel participated in a series of conference calls and meetings in which information from the literature search was extracted and incorporated into the original algorithms. Information from the literature was supplemented by the consensus opinion of the panel when necessary. Multiple iterations of the guideline were then completed and reviewed by panel members and NASS leadership. Modifications (when supported by references from the literature) were then incorporated by the panel chairman.

Strength of Recommendation*:* The strength of the guideline recommendations for or against an intervention was graded as follows:

A Type I evidence or consistent findings from multiple studies of types II, III, or IV
B Types II, III, or IV evidence and findings are generally consistent
C Types II, III, or IV evidence, but findings are inconsistent
D Little or no systematic empirical evidence

Revision Plans: The guideline will be reviewed in 2007.

Definition of Terms:

Musculoskeletal Specialist: Any licensed medical doctor who has completed a resident training program focused on the management of musculoskeletal conditions, including but not limited to: orthopaedic surgeons, neurologists, neurosurgeons, and rheumatologists.

UNIVERSE OF ADULT PATIENTS WITH LOW BACK PAIN AND SCIATICA-ACUTE PHASE I

Definition of the Problem
At least 90% of the population at one point or another during their lifetime will experience low back pain.

Recommendations
Certainly the vast majority of patients presenting with low back pain will be treated in a non-operative fashion. A history is obtained from the patient upon the initial visit, followed by an appropriate physical examination. When evaluating patients with low back pain, it is important to consider the critical exclusionary diagnoses, most important of which are fracture, infection, tumor, progressive neurological deficit, and cauda equina syndrome. Once these more serious conditions have been excluded, treatment should begin with activity modification according to the severity of the symptoms, medications, analgesics, muscle relaxants, self-applied thermal modalities, physical therapy, and manual therapy. Short (no more than two days) episodes of bed rest may be used as the modification of activity. An active exercise program is appropriate **["B" recommendation (references 97, 100, 107, 109, 120)]**.

Expected Clinical Results
The expected clinical results for the overwhelming majority of patients will be a favorable response in a relatively short period of time to a course of non-operative, non-invasive therapy. If the patient responds favorably to the above program, then no further treatment is necessary; if not, then the history, physical exam, and review of exclusionary diagnoses are repeated upon return visits with the physician. If no response at four to six weeks, then a diagnosis is obtained from diagnostic studies (e.g. X-Ray, MRI) and specialized care, as delineated in the Phase II Clinical Guideline on Low Back Pain is warranted.

Alternative approaches
All forms of non-operative treatment would be available, while operative interventions in the early course of the disease would be reserved only for the exclusionary diagnoses such as a progressive neurologic deficit, fracture, infection, tumor, or cauda equina syndrome.

Future Research Recommendations
Prospective, randomized, double blind trials of each of the different treatment methods and modalities would be very beneficial in helping to establishing an evidence-base for all available treatment options.

ADULT PATIENTS WITH LOW BACK PAIN/SCIATICA (ACUTE) PHASE II

DIFFERENTIAL DIAGNOSES

Herniated Nucleus Pulposus/Herniated Lumbar Disc

Definition of the problem

A herniated lumbar intervertebral disc is the most common cause of radicular pain to the lower extremities. The lumbar discs are subjected to repeated deformations and large loads with physiologic motion of the spine. In some individuals fragmentation of the disc may result followed by annular rupture and finally, a herniation of the nucleus pulposus into the spinal canal. The acute manifestation of a symptomatic herniated nucleus pulposus is a segmental neurologic deficit secondary to root compression. The radicular nature of the pain is aggravated by motion of the spine, coughing, sneezing or any mechanism that causes increased pressure to the root. Compression of the root may also cause paresthesias, loss of a deep tendon reflex, and weakness of specific muscle groups. A herniated nucleus pulposus is most commonly seen in those patients from twenty to fifty years of age.

Recommendations

The initial evaluation of the patient should include the location and distribution of the pain. Progressive annular rupture may present with back pain with a non-radicular pain. A herniated nucleus pulposus with root compression presents with a true radicular pattern of pain along the affected root. A neurological exam of the lower extremities should include, and not be limited to, sensation to touch, motor testing, deep tendon reflexes and the presence or absence of pathologic reflexes. Diagnostic studies should be used to confirm the diagnosis. The most common, sensitive and specific is the MRI of the lumbar sacral spine **["B" recommendation (references 135, 138, 142, 168)]**.

The differential diagnoses should include epidural abscesses, tumors, spinal meningiomas and neurofibromas. Bony compression resulting from osteoarthritis and RA may also compress isolated nerve roots. Diabetes and Herpes Zoster may also cause radiating symptomatology.

Initial treatment may include a period of bed rest not to exceed 2 days. During this period, analgesic and NSAIDs may be administered. If the pain persists, epidural steroids may be considered **["B" recommendation (reference 133, 139, 140, 148, 198)]**. Exercise programs may be instituted if the pain decreases. Surgery should be considered if the pain is persistent and severe, and the history, physical findings and diagnostic studies are compatible with a specific root lesion. Early surgical intervention should be considered if the pain is increasing in severity, or if motor, bowel or bladder dysfunction is present **["B" recommendation (reference 125, 152, 155, 176, 190)]**.

Clinical Outcomes
The majority of patients presenting with radicular pain secondary to a herniated lumbar disc will respond favorably to the above program. Reduction of radicular pain and return to normal activities of daily living should be expected. For those patients that do not respond, a re-evaluation of the clinical and medical history and further confirmatory studies are recommended **["B" recommendation (reference 125, 152, 155, 176, 190)]**.

Alternative Approaches
In the absence of severe neurological compromise, a repeated course of pain management with epidural steroids in conjunction with lifestyle modification, vocational alternatives, psychological support, intermittent NSAID usage and vertebral manipulation may be considered **[“B" recommendation (references 125, 133, 139, 140, 141, 148, 152, 155, 176, 190, 198, 202, 205, 209, 215)]**.

Future Research Recommendations
Randomized control trials focused on treatment outcomes are needed. The studies should include validated functional outcomes/economic outcomes as a function of the type of disc protrusion (bulging, herniated, and extruded), specific finding on MRI studies, and the type of treatment (manipulation, epidural steroids, laminectomy / micro-discectomy and exercise training.) The panel recommends the use of the AAOS Clinical Guidelines on Low Back Pain in the treatment of a herniated lumbar intervertebral disc as the benchmark treatment modality when the above studies are conducted.

<u>Unremitting Lower Back Pain</u>
Definition of the problem
Although unremitting lower back pain that continues for more than 6 months is not a threat to the patient’s life as is a terminal disease, it can be both physically and psychologically debilitating and can be a major threat to a patient’s well-being. Because of the frequently enigmatic origins of this condition, results of diagnostic evaluation can be ambiguous and therapeutic interventions are frequently ineffective in providing long-term relief. This diagnostic uncertainty and the resulting frequent failure of therapeutic interventions have led to a disproportionately high allocation of healthcare resources to the relatively small percentage of patients with lower back complaints that experience this unremitting, chronic pattern.

Recommendations
A thorough history and physical examination, and review of routine imaging, will help to identify patients with exclusionary diagnoses who should be referred to a specialist. The MRI is recommended as the diagnostic test of choice in chronic, unremitting lower back pain when additional diagnostic information is required **[“B” recommendation (reference 1)]**. Once an exclusionary diagnosis has been ruled out, reassurance and non-operative care are the cornerstones of treatment. Unlike the pain of a life-threatening disease or injury, the pain of

unremitting lower back pain does not necessarily imply significant tissue damage or a threat to the patient's existence. Reassurance of this fact is critical to a patient's well being. Furthermore, since diagnosis is difficult and surgical outcomes often disappointing, non-operative care is the treatment of choice in most cases of unremitting lower back pain. The chronic use of CNS-affective analgesics (narcotics) is to be discouraged because of their depressive side effects and addictive potential when used for a prolonged time. When a patient presents for treatment already utilizing these drugs in frequent or high doses, consideration of detoxification is warranted.

After evaluation and discussion of the patient's condition, the treating physician and the patient may chose one of two general courses of further treatment. In most cases the choice will be to pursue more intensive, non-operative care. The use of passive or manipulative therapy in chronic, unremitting back pain has little consistent support in the literature reviewed. The use of exercise and exercise-based therapy, however, is supported by a majority of the literature **["B" recommendation (references 227, 251, 256, 272, 273)]**, and is important in minimizing the symptoms of chronic lower back pain. Activity is favored over passivity in treatment.

Depression and other psychological barriers to treatment are often encountered in patients with unremitting lower back pain. When psychosocial factors are identified and appear to be influencing treatment, they should be evaluated and treated, if possible **["B" recommendation (references 228, 247)]**.

The use of epidural steroid injections, therapeutic facet injections and trigger point injections for improvement in long-term outcomes of unremitting lower back pain is <u>not</u> recommended **["B" recommendation (reference 102, 272)]**. These injection techniques may, however, have a very limited role in the treatment of an acute exacerbation superimposed upon the chronic and unremitting condition to establish pain control **["C" recommendation (reference 102, 272)].**

Finally, for a small subgroup of recalcitrant patients that have failed less intensive treatment, a combination of non-operative treatments with an emphasis on activation and the elimination of physical and psychosocial barriers in a multispecialty program of functional restoration may be helpful **["B" recommendation (references 230, 269)]**.

In choosing to pursue consideration of operative treatment in a small number of patients, the treating physician may suspect a symptomatic, anatomic lesion that requires further diagnostic evaluation. Further diagnostic evaluation should only proceed if the treating physician and the patient both feel operative intervention is an option. Because good surgical outcomes remain elusive in unremitting back pain, additional non-operative care could reasonably be recommended at this point. However, a high suspicion of a symptomatic and correctable lesion that would doom conservative care could also be used to recommend further

diagnostic work up for possible operative intervention. As noted above, the MRI is the test of choice for evaluation beyond routine lumbar spinal x-rays with flexion and extension views to detect instability. It is the most sensitive and also most specific of current imaging techniques and should be used to guide further investigation. The appearance of an abnormality on an MRI, however, is frequently insufficient to commit a patient with unremitting lower back pain to surgical intervention. There is demonstrated a high frequency of similar changes in the MRIs of asymptomatic individuals with no history of back pain. Thus there would appear to be a role for evocative testing to stimulate areas of abnormality identified on MRI in an attempt to identify one or more of these abnormalities as in fact the source of the patient's back pain. The discogram is one such test.

The discogram is a sensitive but not very specific test for anterior column pain sources and thus should not be used alone to determine the need for surgical intervention. Likewise there is support for the use of facet blocks as a diagnostic test for a posterior spinal column pain source. It must be noted, however, that neither of these tests has level I or II evidence to support their ability to consistently predict good surgical outcomes. Furthermore, the concurrent existence of significant psychological barriers to wellness reduces the predictive value of these tests even further. When a painful anatomic lesion can be appropriately identified with a thorough and complete workup and when no significant psychosocial barriers exist to wellness, lumbar fusion may be recommended as a treatment for disabling low back pain in these appropriately selected patients **["B" recommendation (reference 250)]**.

Clinical Outcomes/Alternative Approaches
If diagnostic evaluation does not reveal a surgically correctable lesion or if the patient is felt to have psychosocial barriers that disallow valid evaluation or surgical treatment, then the non-operative arm of treatment is medically reasonable and surgery should not be attempted. Likewise, if surgery is elected and the surgical outcome is not satisfactory, then the non-operative arm of treatment is medically appropriate.

Future Research Recommendations
The revision panel for the clinical guideline on low back pain feels that, in the area of Unremitting Low Back Pain, additional outcomes studies are warranted to compare the outcomes of surgical intervention in the form of lumbar fusion for axial pain versus non-operative care. Studied patients should be clearly delineated by precisely defined criteria and fully worked up by a predefined protocol prior to randomization to an operative and non-operative treatment condition. These studies should be of sufficient size to generate strong statistical power and should include validated economic and functional outcomes measures. Follow-up should exceed two years, if possible.

Spondylolysis, Lytic Spondylolisthesis, or Degenerative Spondylolisthesis (SLIP)

Definition of the problem

Spondylolisthesis is defined as anterior subluxation of one lumbar vertebra over another. It is present in 5% of the adult population, with the degenerative variety afflicting up to 30% of women over 60 years age. One of the challenges in diagnosing spondylolisthesis is differentiating the long-standing isthmic spondylolisthesis from a new degenerative process at another level.

Recommendations

The patient should be treated with the usual Phase I treatment and assessment of critical exclusionary diagnoses. Once the diagnosis of spondylolisthesis has been made, an evaluation for instability and neurologic deficit is then done. If this is positive, then an ongoing more sophisticated diagnostic battery of tests including MRI, CT, myelogram/CT, bone scan, discography, or facet lysis injections would be appropriate. The vast majority of patients can be successfully treated non-operatively **["B" recommendation (reference 26)]**. The non-operative program would include non-steroidals, analgesics, active exercise, physical therapy, bracing, and possibly injections. If the patient fails non-operative treatment, then surgery would be considered. The mainstay of surgery for any spondylolisthesis would be fusion **["B" recommendation (references 13, 24, 27, 31, 33, 80)]**. This then comes with the option of decompression and/or instrumentation.

Expected Clinical Results

The vast majority of patients with spondylolisthesis-related back pain will be successfully managed non-operatively. If surgery is necessary and undertaken, then this would have a reasonable likelihood of returning the patient to an acceptable level of function.

Alternative Approaches

The non-operative methods that include all aspects of lower back care but these have not been demonstrated to have outcomes that warrant current recommendations.

Future Research Recommendations

Additional prospective randomized double-blind studies employing validated functional outcomes measures are needed.

Lumbar Spinal Stenosis

Definition of the problem

Lumbar spinal stenosis involves the clinical symptoms of lower extremity neurogenic claudication or radiculopathy. The symptoms of neurogenic claudication are aggravated by standing erect as well as walking and are relieved by forward flexion of the spine or sitting. Symptoms usually involve groin, thigh and buttock pain with a variable neurological picture. Patients usually present in the fifth decade or greater. The physical exam may demonstrate ambulation with

a forward flexed fashion as well as symptomatic aggravation with lumbar spinal extension.

Recommendations
The initial goal in the treatment of patients with lumbar spinal stenosis is to provide relief of pain and to return patients to their normal activities of daily living. Clinically mild to moderate symptoms may be treated with NSAIDs, analgesics, active exercise, physical therapy, and/or a bracing trial **["B" recommendation (references 297, 301, 304, 327, 341)]**. If the treatment response to these modalities is poor, then confirmatory studies are undertaken. If these studies are positive then trial of an injection program may be considered or a discussion of surgical options may be undertaken.

For clinically severe symptoms that are confirmed by imaging studies such as MRI, CT, CT Myelogram, EDS a doctor patient discussion of treatment options should ensue. These involve both operative and non-operative options. For those patients that respond to non-operative treatments, a gradual return to normal activities ensues. For those patients that do not respond to non-operative treatments, surgical options are proposed.

Posterior surgical decompression is undertaken for the symptomatic patient that fails to respond to non-surgical modalities or presents with progressive neurological deficit **["B" recommendation (references 306, 307, 313, 317, 318, 321, 322, 323, 324, 326, 331, 332, 338)]**. If greater than 50% of the facet joints are removed bilaterally, then fusion with or without instrumentation is considered **["B" recommendation (references 291, 295, 302, 305, 319, 325, 328, 341)]**. Patients that respond to surgical treatment may gradually resume normal activities. If patients fail surgical treatment, consider a reevaluation of the clinical findings and the need for additional confirmatory imaging.

Expected Clinical Results
The expected clinical result is to return patients to normal activities as well as decrease their overall pain level.

Alternative Approaches
Alternative approaches may include lifestyle modifications, repeated pain management trials, and/or a variety of assistive devices such as canes and walkers.

Future Research Recommendations
Additional prospective, randomized double-blind studies measuring employing validated functional outcome measures are needed. One such study should explore the effectiveness of epidural steroid injections versus placebo in improving patient outcomes, and its impact in moving patients into a period of remission without surgery.

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Interpreting the Guideline Symbols

Unshaded boxes represent points in the algorithm where actions are to be taken or information is to be collected (i.e., the "Significant History" information box asks the reader to take a medical history).

Shaded boxes are text blocks and are used to provide detailed information about an action to be taken or information to be collected (i.e., the "Significant History" text block defines the history information that is critical to collect to deal with the diagnoses addressed in the algorithm).

Diamonds represent decision points (i.e., the "Response to Initial Treatment" diamond asks the reader to decide at what level an intervention has been successful).

Ovals indicate end points (i.e., the "Refer to Specialist" circle indicates that the non-specialist should release the patient into the care of a specialist).

Arrows and connector lines mean that the reader should continue on in the direction indicated.

Broken arrows mean that readers should be aware that further diagnostic and treatment options exist, but that the remainder of the algorithm is intended for use by specialists following referral or consultation with the first contact physician.

* *Asterisks* indicate a continuation of the algorithm to another page.

Clouds indicate that an intervention is highly controversial and although the information or procedure may be used in practice by some physicians, very little sciencitic evidence exists to support its effectiveness.