INTERVENTIONAL PAIN MANAGEMENT TREATMENT PROTOCOL

EPIDURAL STEROID INJECTIONS IN THE MANAGEMENT OF SPINAL PAIN

A. BACKGROUND

Epidural glucocorticoid and local anesthetic injections can be considered as part of a treatment program for radicular pain syndromes secondary to a herniated disc, degenerative disc disease, or spinal stenosis. The purpose of spinal injections is to facilitate active therapy by providing short-term relief through pain and inflammation reduction. The goal of such injections is to deliver the active medication with minimal systemic effects (vs. oral steroids) as close as possible to the target tissue.

There are three most frequently used approaches: caudal, interlaminar,and transforaminal. Of these three, the most common is the use of transforaminal epidural injection, performed by injection immediately adjacent to the dural sac in the posterior spinal column, with subsequent diffusion to the herniated disc or other inflamed, irritated or impinged neural structures. Fluoroscopic guidance of needle placement has been shown to improve the accuracy of the placement of the injection; however, whether the clinical outcome is improved with this remains somewhat unclear.

The subspecialty disciplines of the physicians performing the injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner should document hands-on training through workshops of the type offered by organizations such as the International Spine Intervention Society, North American Spine Society, American Society of Interventional Pain Physicians, and others, with post course proctoring and/or fellowship training with interventional training. Also essential is being knowledgeable in radiation safety and credentialed by a hospital or surgery center.

Epidural injections may be performed in the cervical, thoracic, lumbar, as well as sacral (caudal) regions. Caudal epidural steroid injections may be used for patients with leg pain of sacral origin or in whom direct access to the lumbar region is difficult, or not possible due to previous surgery.

Epidural injections are invasive, have a low risk of adverse effects, and are relatively costly. They are most commonly offered as an option in acute radiculopathy as a second line treatment after prior treatment with NSAIDS, possibly a short course of an oral steroid (with equivocal evidence of effectiveness), and a waiting period of at least 3 weeks with/without other adjunctive treatment measures (exercise, spinal manipulation, etc.).

Lumbar injections have been shown to reduce radicular pain, and their use may have the effect of decreasing surgical rates for specific spinal disorders. The effect of the injections on pain is not intended to be curative, but more palliative in nature. Repeat injections may be beneficial in the management of patients who have a favorable response to an initial injection.

The use of lumbar epidural steroid injections (ESI) in the treatment of nonradicular, axial back pain is not strongly supported by the data at present. Therefore, these should not be considered as part of the routine management of these conditions. Prognostic indicators that often predict which patients are likely to benefit from lumbar transforaminal ESI include:

- Presence of a "contained" disc herniation with abutment, but not displacement of the nerve root.
- Presence of symptoms for less than 3 months.
- Presence of confirmatory EMG positive findings.
- Presence of radicular pain from a herniated intervertebral disc and central stenosis and/or lateral recess stenosis at the supra-adjacent intervertebral disc.
- Presence of disc herniation that does not extend through the posterior longitudinal ligament.

Therapeutic spinal injections have not been proven to change the long-term course of most patients with spinal pain. They have a limited role in treatment and should be only used in a small patient subset where the criteria outlined in this protocol have been clearly met. Pain relief for at least one month in greater than 50% of patients, with half of these patients continuing to benefit from treatment for a year or more, is anticipated. As such, there is some evidence that adding steroids to a bupivicaine solution may reduce the frequency of surgery in the first year year after treatment. Some studies have shown benefits for the non-surgical group persisting for at least 5 years, regardless of the type of block provided. Injections may be used for patients who are having significant pain that is interfering with daily functions and the active therapy necessary for recovery, despite medical pain management and active therapy. An MRI or CT scan is often indicated before injection to localize pathology and rule out injection contraindications. There is strong evidence that ESI has no short or long term benefit for non-radicular low back pain.

As noted above, the purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the discretion of the interventionist. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

B. OUTPATIENT TREATMENT

Since the pain relief from epidural steroid injections is usually brief and, by Definition, chronic non-specific back pain and chronic radicular pain (with or without prior back surgery) are chronic problems, injections are not recommended as a transient treatment for these long-term problems, unless there is specific exacerbation that indicates their use. The concurrent use of injections during participation in a rehabilitation program may be beneficial.

Injections are commonly performed on an outpatient basis. As noted above,fluoroscopic guidance provides the most accurate method for ensuring injection of the steroid into the desired location. If local anesthetics are also used, proper vital sign monitoring is required, including electrocardiography, blood pressure monitoring, as well as pulse oximetry. Conscious sedation may be required for some anxious patients, but is not usually necessary. Emergency equipment, including but not limited to oxygen, ventilatory tools, laryngoscope, endotracheal tubes, intravenous access supplies and vasopressors must be available, as well as appropriately trained individuals, as per State of R.I. Board of Health requirements, as well as any other applicable regulatory medical agencies or groups. Commonly, long acting steroids (dexamethasone) are used, with the most common anesthetics being lidocaine and/or bupivicaine. Corticosteroid dosing is most often based on one third (1/3) the dose associated with adrenal suppression, per injection.

Epidural steroid injections are primarily intended for reducing inflammation around the nerve root for primarily radicular pain. Due to the long acting nature of the steroid preparations used, they should not be performed at less than two (2) week intervals. Optimally, injections should occur at 2-6 week intervals. No more than two injections should be used to attempt to achieve a beneficial response in the first instance, and thereafter, up to three injections in a six month period, and not more than six (6) in a twelve (12) month interval should be used to reinstate and maintain benefit once it has been achieved at a specific nerve root level. In order to justify repeat treatment, benefit should be evident in the form of reduced pain and/or improved function, along with reduced need for other health care. If a lack of response is seen after two epidural steroid injections, no further injections should be performed at the same level.

Epidural injections should be scheduled separately, and effects of each evaluated, rather than scheduling a series of three. A third epidural injection is not recommended if, following the first two injections, there has not been a significant reduction of targeted symptoms, symptoms have resolved, or if no documented increase in physical activities/function occurs.

In patients who respond to an injection with 3-6 weeks of temporary, partial radicular pain relief, but then develop worsening pain and functional loss, but do not wish to proceed to surgery, a repeat epidural injection may be an option. If measurable improvement is noted, repeat injections at 3, 6, or 12 month intervals may be used, until stabilization of symptoms occurs.

C. MEASURABLE PARAMETERS ASSOCIATED WITH INJECTIONS

By themselves, injections are not likely to provide long-term relief. Active rehabilitation with concurrent modified work best achieves long-term relief by increasing active range of motion, strength, and stability. Documentation of patient response regarding the type and degree of response to specific symptoms should be provided by the interventionalist. Three or four measurable physical functions that are restricted at the time of the injection should be objectively assessed shortly after the injection (range of motion, walking, standing, lifting), in addition to validated

patient reported outcome measures. Patients pursuing injections should commit to continuing appropriate exercise with functionally directed rehabilitation, usually beginning within 7 days of injection. Active treatment, which patients should have prior to injections, usually up to a total of 6 sessions of physical therapy, will frequently require a repeat of the sessions previously ordered.

Functional change is the most important criteria supporting the use of interventional techniques, not the patient's report of pain (as this is too subjective and widely varies from patient to patient). Increased range of motion, increased job task accomplishment, increase in physical therapy progress, and decreased pain medication use can all act as appropriate barometers of success, and should be documented in post-injection evaluation reports. In addition, validated patient reported outcome measures (ODI, RMDQ, or FOTO, for example), are useful in determining successful injection outcomes.

If the first injection does not provide a documented improvement in function, and a diagnostic response with temporary and sustained pain relief substantiated by accepted pain scales (i.e., approximating 50% pain reduction on a visual analog scale), a second injection can be pursued; however, if two injections show no benefit in outcomes, a third injection is unlikely to be successful.

Electromyography may be helpful in predicting the likelihood of improvement after lumbar epidural steroid injections. A retrospective review of 39 subjects demonstrated that patients with EMGs that were considered positive for radiculopathy were significantly more likely to have functional improvement using the Oswestry Disability Index (ODI) after an epidural steroid injection than patients with a negative or normal EMG examination.

D. PATIENT SELECTION: PRIOR TO FIRST INJECTION

Therapeutic injections should be used after previous evaluation, treatment, and imaging studies have established pathology which has not clinically improved after active engagement (6-8 weeks) of physical therapy, and in patients who otherwise qualif y for more invasive procedures and may need injections due to their inability not to undergo surgery, or their wish not to undergo surgery. The goal of injection(s) in this group is to afford a few weeks of partial pain relief while spontaneous recovery occurs, or allowing for the patient to tolerate other treatments, and therefore facilitate more active and aggressive pursuit of rehabilitative goals and restoration of function.

The following patient sets may have epidural injections, when diagnostic epidural injections are positive:

1. When radicular findings secondary to a herniated disc is present, and the patient meets all of the surgical indications at approximately 6-8 weeks post active therapy.

2. An acute disc herniation if, after approximately 6 weeks of initial oral analgesic and conservative, the patient has continued pain interfering with most ADL function, and is unable to tolerate therapy, has pain greater than 7/10 in severity and has dermatomal pain distribution, with a corresponding herniated disc on MRI/CT consistent with the clinical presentation.

3. Patients with spinal stenosis, who has completed 6-8 weeks of active therapy, with persistent radicular findings and difficulty with activities, thus meeting surgical intervention criteria (includes diagnostic injection). If this instance, if the patient does not wish to pursue surgery after the first injection, two more injections may be provided if the original diagnostic intervention was successful.

- **DIAGNOSTIC CRITERIA**

1. Pertinent History and Physical Findings

   a. A pattern of pain in the upper extremity, thoracic region, or lower extremity with the characteristics as well as specific distribution of a known nerve root, known as a radiculitis or radiculopathy. Radiculopathy refers to a sensory and/or motor dysfunction in the discrete distribution of an affected nerve root. Most cases result from either compression of, or inflammation to the nerve root as it exits the spinal canal, most commonly secondary to a disc protrusion/herniation. Such pain may be seen in the absence of previous surgery, but can also be seen following failed post-operative disc surgery. Physical findings strongly suggestive of a radiculitis/radiculopathy (positive straight leg raise testing, reflex diminishment in the affected limb, motor weakness and/or sensory dysesthesias or hypoesthesias, particularly in a pattern consistent with specific nerve root(s)) may accompany subjective complaints.

   b. For epidural steroid injections throughout the spine, pain may be distributed in a specific nerve root pattern (dermatome), and/or myotomal distribution. In addition,for thoracic epidural injections, pain may be distributed in a "barrel stave" fashion, from the mid back, then extending anteriorly to the side and chest, in accordance with the underlying thoracic nerve root inflammation. Anatomic variation can exist in these nerve root distributions.

   c. Particularly in the early stages, entire nerve root distribution may not be affected. The duration of symptoms may play a role in decision making regarding timing of injections. Subacute radicular pain (pain lasting 3 weeks or longer) that has not responded to more conservative measures (particularly when the presumed etiology of this pain is well identified and potentially reversible with a steroid injection) may form a historical foundation for proceding with injection. Patients with chronic back pain with exacerbations also fall into this group. As stated previously, the goal of injection(s) in this group is to afford a few weeks of partial pain relief while spontaneous recovery occurs, or allowing for the patient to tolerate other treatments, and therefore facilitate more active and aggressive pursuit of rehabilitative goals and restoration of function.

d. Evidence supporting the efficacy of ESI in the treatment of lumbar radicular pain in the setting of foraminal and central stenosis is inconclusive at present.

- **APPROPRIATE DIAGNOSTIC TESTS AND EXAMINATIONS**

The current practice in the U.S. is to obtain either a CT or MRI scan prior to the performance of an epidural injection. There are, however, studies of good quality showing effectiveness of injections based on clinical examination to address the target level for injection. Benefits of pre-procedural imaging include a greater safety margin in the determination of the entry level, the ability to rule out/in other pathology, as well as determining the presence of a surgical condition (thereby contraindicating the use of the epidural injection). Studies are ongoing, however, regarding whether imaging is required or not, as well as the benefit magnitude obtained from imaging.

The use of an EMG/NCVS can be considered, particularly in cases where the symptoms/physical findings and, possibly, imaging studies are ambiguous, or do not provide a clear guide as to the underlying pathology attributable to the presenting complaints. In some instances (e.g., presence of a medical condition contraindicating a specific imaging study, etc.) other studies (CT myelogram, discography) may be considered to confirm the diagnosis prior to proceeding to epidural injection.

- **INJECTION COMPLICATIONS AND CONTRAINDICATIONS**

  - **CONTRAINDICATIONS TO THERAPEUTIC INJECTIONS**

Informed decision making should also be documented for injections and all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis.

Absolute contraindications to therapeutic injections include: (a) bacterial infection (systemic or at injection site); (b) bleeding diatheses; (c) hematological conditions; (d) pain of three points or less on a 10-point visual analog scale measurement at the time of injection; (e) possible pregnancy (excepting the use of LESI in late pregnancy, without fluoroscopy); and (f) poorly controlled diabetes mellitus for steroid injections.

Relative contraindications to therapeutic injections include: (a) allergy to contrast; (b) somatization disorders; (c) poorly controlled congestive heart failure for steroid injections; (d) risk factors for osteoporosis and uncontrolled hypertension., as well as concurrent use of drugs affecting coagulation; (e) poorly controlled congestive heart failure.

SACROILIAC JOINT INJECTIONS

A. Background: The sacroiliac joint (SIJ) is an established source of pain, with documented innervations. However, the prevalence of SI joint or posterior SI

ligament pain in the general population is unknown. In addition to the joint, other structures, such as the posterior sacroiliac ligaments, are innervated and are, therefore, potential pain sources. Posterior sacroiliac complex pain refers to pain as a result of inflammation of these ligamentous structures. Local anesthetic blocks of the lateral branches of the sacral dorsal rami have been shown to diminish inflammation of the interosseous and dorsal sacroiliac ligaments, but not the sacroiliac joints.

B. <u>Description:</u> In general, this involves the injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance. The injection may include the use of corticosteroids. Sacroiliac (SI) injections have been used to diagnose and treat pain from this area. Lateral branch blocks and radiofrequency ablation have also been used to diagnose and treat pain from the SI joint/SI joint complex. Certain conditions, such as older patient age, history of prior lumbar fusion, and trauma are associated with SI related pain. Unfortunately, there is a high false-positive rate with injections into the SI joint. This stresses the importance of documentation of at least three exam maneuvers (Gaenslen's, FABER, thigh thrust, distraction, sacral thrust and/or compression tests) prior to an injection. SI injections are commonly used either to facilitate the diagnose of SI inflammation, or for therapeutic gains.

C. <u>CLINICAL INDICATIONS AND IMAGING:</u>

- Are organized by primary location of pain:
    - Pain over the SIJ
    - Pain over the SIJ and referred into the leg
    - Pain over the SIJ with referral into the groin
    - Maximal ipsilateral pain above the L5 vertebrae
    - Suspected spondyloarthritis has a negative correlation with success
- Physical examination findings are a significant indicator of appropriateness of intervention:
    - Three or more positive provocation SIJ tests
        - Can be effective, though, in presence of one or two positive provocation tests, depending on the other scenario variables.
- Not appropriate to perform injections in the absence of a clinical exam, or in those patients with no positive provocation maneuvers.
- Since these procedures are invasive, less invasive or non-invasive procedures should be considered first.

- Considered when pain present for more than one month, has an intensitiy of greater than 4/10, and is causing functional limitation, regardless of whether or not conservative therapy had been provided.

- Appropriate for pain of lesser intensity and duration if pain is causing functional limitation and conservative treatment had been provided, with continued symptomatology.

D. <u>DIAGNOSTIC SI INJECTIONS.</u>

- **<u>INDICATIONS:</u>** to aid in the diagnostic work-up of low back pain when all of the following criteria are met:

  - The presence of nonradicular, usually unilateral pain distal to the L5 vertebrae, over the area of the posterior SI joint.

  - A full physical examination demonstrating very focal, localized tenderness to the sacral sulcus (at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine (PSIS)), without tenderness elsewhere.

  - The absence of any other significant sources of pain.

    - A positive response to at least three of the diagnostic physical tests listed above (Gaenslen's, etc.).

  - Imaging guidance: fluoroscopy or CT guidance should be utilized in the performance of this procedure.

  - Injectate volume: no more than 2 mls. of anesthetic should be injected, without addition of steroid.

  - Interpretation of results: a diagnosis of SI joint pain is confirmed with at least a 75% reduction of pain lasting the anticipated duration of time based on the type of anesthetic agent injected, with results repeated with a subsequent repeat confirmatory injection.

E. <u>THERAPEUTIC SI INJECTIONS.</u>

- **<u>INDICATIONS</u>**: Identical to those criteria, listed above, for the use of diagnostic SI injections.

- **<u>ASSOCIATED DIAGNOSTIC TESTING:</u>** imaging such as radiographs, MRI, or CT scans can be useful in the exclusion of other potential sources of nonradicular back pain, as well as the determination of SI inflammatory conditions or lesions/pathologic conditions or "red flags", as well as to

exclude conditions that would contraindicate or limit the effectiveness of the injection. The medical record must support the necessity of advanced imaging, when recommended.

- As with epidural injections, any improvement in physical functions that are impaired and can be objectively reassessed should be measured , using identical criteria to those outlined in the epidural section of this protocol. Significant positive responses, both in pain measurement and physical function, support successful treatment outcomes.

- Injections of steroid with local anesthetic, injections of steroid alone, or lateral branch blocks are appropriate options.

- Can consider therapeutic injection if initial diagnostic injection provided greater than 75% relief, regardless of duration of relief. Further injections are generally not recommended if pain relief is less than 50%. Injection of steroid alone only appropriate if at least 75% relief for 2 months with first injection.

- Frequency and optimum duration: 2 to 3 injections per year. Injections may be repeated if they result in increased documented functional benefit for at least 3 months and significant improvement in pain scales (as measured by accepted pain scales (such as VAS), as well as documentation of improved parameters of physical functioning. At least 6 weeks or 3 months of functional benefit should be obtained.

- **<u>LATERAL BRANCH RADIOFREQUENCY NEUROTOMY (LBRFN).</u>**

  - Two key factors: symptom duration and degree of pain relief realized during blocks.
    - Patients should have symptoms for a minimum duration of 2-3 months.
    - Less than 50% pain relief from diagnostic injection is insufficient justification to proceed with LBRFN.

    - Higher levels of pain relief and symptom duration correlates with higher appropriateness of indication.

      - The intent of RF is to cauterize the medial branches (L5 dorsal branch or S1-S4 lateral branches). Successful RF Neurotomy usually provides from six to eighteen months of relief. Repeat

neurotomy should only be performed if the initial procedure resulted in improved function for 6 months;

- Repeat LBRFN not appropriate if the first LBRFN results in less than 50% pain relief, or if less than 3 months duration of effect.

- Type and sequence of block performed (intra-articular vs. lateral branch block) has minimal impact of outcome; is most relevant in patients with 50%-75% pain relief and in those with 2-3 months of symptoms.

ZYGAPOPHYSEAL (FACET) INJECTIONS

- **BACKGROUND**: The facet, or zygapophysial, joints are paired diarthrodial articulations between posterior elements of adjacent vertebrae. Spinal facet joints have been implicated as responsible for spinal pain in up to 40% of patients with low back pain, up to 67% of patients with neck pain, and up to 50% of patients with thoracic pain. Paravertebral facet joint/nerve blocks are utilized as a diagnostic, as well as therapeutic tool to determine whether a specific facet joint is responsible for spinal pain. The patient with this condition usually has moderate-to-severe back pain that does not have a strong radicular component, there is no associated neurologic deficit, the pain is typically aggravated by hyperextension of the spine, and there is typically tenderness to palpation of the spine at the level of the suspected joint. Back or neck pain is typically worse than leg or arm pain, respectively, e.g., pain is primarily axial, not radicular.

  Neural blockade is one technique used in chronic pain management. Neural blockade is the interruption of neural transmission by the injection of a local anesthetic agent or other drug. Nerve block therapy can be used to answer specific questions resulting from a careful evaluation of the patient's pain problem and to gain insight into the underlying problem causing the pain. Success of the nerve block is determined by the adequacy of interruption of nerve function, and the effect of that blockade on the patient's pain. The goal of pain management is to achieve optimal pain control, recognizing that a pain-free state may not be achievable; minimize adverse outcomes; enhance functional abilities and physical and psychological well-being; and enhance the quality of life.

  Facet joint arthropathy (joint disease) is diagnosed through a double comparative local anesthetic blockade of a joint, either by intra-articular injection of a small volume of local anesthetic (0.5 to 1.0 ml), or blockade of the medial branch nerves of the dorsal rami innervating the joint with a small volume of local anesthetic (0.5 to 1.0 ml). The diagnosis can be made by a positive but differential

response to local anesthetics of different durations of action injected on separate occasions.

After a needle is placed into the facet joint or adjacent to the target medial branch nerve under imaging guidance, a small volume (0.5 to 1.0 ml) of a short or longacting local anesthetic agent with or without steroid is injected. The patient is then asked to engage in activities that typically elicit or aggravate the pain. Relief of pain for a significant period of time suggests that facet joints were the source of the pain. Pre-procedural and post-procedural pain scores (numeric or Visual Analogue) should be documented, and then compared. If significant pain relief occurs after the injection (a positive response), the patient's response should be monitored and documented with regards to the degree of pain relief, duration of pain relief, and improvement in functional status. A repeat block may be performed only if the patient's pain returns and functional status starts to deteriorate. If significant relief is noted with improvement in functional status, but the pain returns after a period of relief, a second block may be performed at a later date with local anesthetic of a different duration of action in order to rule out a false positive response.

If double-comparative paravertebral facet joint /nerve blocks provide significant pain relief lasting several weeks to months, therapeutic facet joint/nerve blocks may be considered. If double-comparative paravertebral facet joint/nerve blocks provide significant pain relief that is not long-lasting, facet joint denervation may be considered.
For the purposes of this policy, a facet joint level refers to the zygapophyseal joint or the two medial branch nerves innervating that zygapophyseal join

- Facet joint procedures are only appropriate if the patient is suspected of having back pain secondary to facet inflammation, and/or is eligible for increased therapy, such as a rhizotomy, based on the results of the block. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion.

- Since most patients with these conditions will improve significantly over time without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy. It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms.

- Imaging accompanying the procedure: Multi-planar fluoroscopic imaging or CT-guided imaging is required for all procedures targeting the facet joints.

- **<u>INDICATIONS:</u>**

  - Patients who are suspected to have back pain that is facet in origin, based on exam findings and affecting activity; OR

  - Patients who have facet findings with documented findings which consist of pain with extension and lateral bending, with referral patterns consistent with the expected pathologic level. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators.

  - Back or neck pain following whiplash/post-traumatic injury;

  - Back pain greater than leg pain;

  - Neck pain greater than arm pain;

  - Thoracic pain greater than chest wall pain;

  - Back or neck pain associated with suspected motion segment instability/hypermobility or pseudoarthrosis following fusion

  - Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy.

- Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than three levels unilaterally, or two levels bilaterally. A CT or MRI scan usually precedes referral for injections.

- Informed decision making should also be documented for injections and all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis.

- A successful intraarticular facet joint injection requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. Ideally, the evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians.

  Pertaining to radiofrequency ablation neurotomy, to be successful, the results should occur within the expected time frame and there should be pain relief of approximately 50% (demonstrated by pre and post Visual Analog Scale, as well as supporting documentation of functional gains), persisting for a six to eighteen month time period.

  - Therapeutic Paravertebral Facet Joint/Nerve Block
    - Considered if a patient has relief of pain with controlled diagnostic blocks with a combined response from two blocks of several weeks to months.

    - If the patient has relief of pain (positive response), but an insufficient duration of symptom relief, with controlled diagnostic blocks, he/she should be considered for a more definitive procedure such as denervation, after ensuring that the underlying diagnosis is accurate.

    - Frequency of injections: injections should not exceed a frequency of more than once every two months for a specific region (cervical/thoracic, lumbosacral);
      - initial pain relief of greater than or equal to 80%-90% with the ability to perform previously painful maneuvers and persistent pain relief for a minimum of six weeks of at least 50%, with the continued ability to perform previously painful maneuvers.

      - Only paravertebral facet joint/nerves for which there has been a positive response should be injected for therapeutic reasons. No more than two, and occasionally three unilateral or bilateral joint/nerve injections per region would be anticipated per date of service.

      - Only paravertebral facet joints for which there has been a positive response to at least two double-comparative local anesthetic injections should be denervated.

PARAVERTEBRAL JOINT/NERVE DENERVATION.

- the destruction of a paravertebral facet joint nerve by neurolytic agent (chemical, thermal, electrical, or radiofrequency), it involves placing a needle or radiofrequency cannula adjacent to each of the two, or more, medial branch nerves innervating the target joint(s).

- may be considered if double-comparative paravertebral facet joint/nerve blocks do provide significant pain relief, but the pain relief is not long-lasting.
    - Indications: Facet joint arthropathy (joint disease) is diagnosed through a double comparative local anesthetic blockade.
        - failure of conservative therapy
        - All appropriate diagnostic paravertebral facet joint/nerve block studies have been performed.

- Significant pain relief in this instance is defined as greater than or equal to 80%-90% initially, with the ability to perform previously painful maneuvers.
- The effects of denervation should last from six months to one year, or longer.

OTHER PROCEDURES:

There are several other procedures that have been incorporated in the treatment of recalcitrant back pain. As with all of the procedures discussed previously in this protocol, implementation of an appropriate exercise program, with functionally directed rehabilitation, should occur. Patients who are unwilling to engage in this therapy should not receive this procedure.

1. **TRANSFORAMINAL INJECTION WITH ETANERCEPT**

    - Description - Transforaminal injection with a tumor necrosis factor alpha inhibitor is thought to decrease the inflammatory agents which may be associated with the pathophysiology of lumbar radicular pain from a herniated disc. It is *not recommended* due to the results of a study which showed no advantage over steroids or saline injections.

TRANSDISCAL BIACUPLASTY, INTRADISCAL ELECTROTHERMAL THERAPY (IDET), AND OTHER INTRADISCAL ELECTRICAL PROCEDURES.

- Description – Various technologies generally using electrically generated heat or cooled radiofrequency energy to coagulate fissures in the disc and surrounding nerves which could be pain generators. These procedures *are not recommended* due to lack of high quality published data demonstrating effectiveness.

INTRADISCAL REGENERATIVE THERAPY.

- While promising, studies concerning the introduction of various substances, including fibrin, platelet rich plasma, and gene therapies injected into degenerated discs with the intent of the restoration of healthy disc matrix and healing disc disruption are not yet supported by adequate published data to support use.

TRIGGER POINT INJECTIONS AND DRY NEEDLING TREATMENT.

- **DESCRIPTION:** Trigger point injections are a generally accepted treatment. Trigger point treatment can consist of dry needling or injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities.

- **CURRENT EVIDENCE SUPPORTING USE:** There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response. Needling must be performed by practitioners with the appropriate credentials in accordance with state and other applicable regulations. There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

- **INDICATIONS:**

    - Dry needling should only be considered appropriate for use after other, less invasive modalities (physical therapy, heat/ice, electrical stimulation) have been tried and failed.

    - Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as active therapy programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress.

    - As with all interventions, appropriate documentation of improved pain scales, as well as functional gains, need accompany injections/dry needling.

- Patients should continue in an aggressive aerobic and stretching therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

- Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 6-week time frame. However, trigger

point injections may be occasionally effective when utilized in the patient with immediate, acute onset of low back pain.

- Complications: Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, penetration of viscera, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

    - Time to produce effect: Local anesthetic 30 minutes; 24 to 48 hours for no anesthesia.
    - Frequency: Weekly. Suggest no more than 4 injection sites per session per week to avoid significant post-injection soreness. Increasing duration of benefit during the three initial treatments should be documented prior to consideration of further treatments.
    - Optimum duration: 4 Weeks. However, an initial trial of three injections, with objective improvement documented, must precede ongoing treatment. If no significant objectifiable improvement is seen after three injections, no further injections should be pursued.
    - Maximum duration: 8 weeks. Occasional patients may require 2 to 4 repetitions of trigger point injection series over a 1 to 2 year period.

GENERAL CONSIDERATIONS WITH INTERVENTIONAL THERAPY

- It is usually not appropriate to provide an interlaminar epidural/intrathecal injection, a transforaminal selective epidural (or selective nerve root injection), facet joint/nerve block, sacroiliac joint injection, lumbar sympathetic block, or other nerve block on the same day. Therefore, only one of these procedures is allowed on a given day, unless conditions are met as described immediately above for paravertebral and sacroiliac joints or one of the following conditions occur and are documented in the medical record:

    - If more than one type of diagnostic injection is performed on the same day, the anesthetic response to the first injection must be assessed and demonstrate incomplete pain relief prior to proceeding with the additional injection. Otherwise it would be impossible to determine which injection resulted in pain relief.
    - Multiple pain generators are present and are clearly documented in a patient on anticoagulants, requiring the anticoagulants to be stopped for the injection(s).
- General anesthesia is contraindicated for diagnostic blocks. Further, monitored anesthesia care or heavy sedation may provide false-positive results.

- Once a structure is proven to be negative, no repeat interventions should be directed at that structure unless there is a new clinical presentation with symptoms, signs, and diagnostic studies of known reliability and validity that implicate the structure.

PROTOCOL HISTORY:
Passed: 4/27/1993 as "Caudal Epidural Blocks in the Management of Lower Extremity Pain"
Amended: 6/9/1998 as "Epidural Nerve Blocks and Epidural Steroid Injections in the Management of Spinal Pain"
Amended: 11/19/2002
Amended: 4/27/2010
Amended: 4/26/2016 as "Interventional Pain Management Treatment Protocol"