Evidence-Based Medicine in Interventional Pain Management

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Evidence-based medicine (EBM) is a form of medicine that aims to optimize decision-making by emphasizing the use of evidence from well designed and conducted clinical research.

Numerous jurisdictions have adopted evidence-based treatment standards for case management and determination of medical necessity in workers compensation.

It is recognized that there has been a lack of strong evidence to support many commonly used interventional pain therapies.
EBM in Arizona

- Statutory requirement in place to develop and implement a process for the use of evidence-based treatment guidelines
- ICA Director's Advisory Committee created in 2012 to provide recommendations regarding the development and implementation of this process
- Consensus reached that it is appropriate to use the Work Loss Data Institute's Official Disability Guidelines ("ODG") starting with the treatment and management of chronic pain and use of opioids
- ICA adopted these recommendations on 5/22/14
Levels of Medical Evidence

- Ia - Evidence from Meta-analysis of Randomized Controlled Trials
- Ib - Evidence from at least one Randomized Controlled Trial
- IIa - Evidence from at least one well designed controlled trial which is not randomized
- IIb - Evidence from at least one well designed experimental trial
- III - Evidence from case, correlation, and comparative studies.
- IV - Evidence from a panel of experts
Most Common Pain Procedures

- Epidural injections
  - Cervical, thoracic, lumbar
  - Interlaminar, transforaminal, caudal
- Sacroiliac joint (SIJ) injections
- Facet procedures
  - Intraarticular, MBB, RFA
- Trigger point injections
- Sympathetic blocks
- Piriformis injections
Implantable Therapies

- Neurostimulation
  - Spinal cord stimulation (SCS)
- Implantable drug delivery systems (IDDS)
“Unconventional” Therapies

- Acupuncture
- Regenerative Medicine
  - Prolotherapy/Sclerotherapy
  - Stem cell autologous transplantation
  - PRP
- Intradiscal Procedures
  - Intradiscal electrothermal therapy (IDET)
  - Nucleoplasty (Coblation)
- Adhesiolysis (Racz neurolysis)
- Botox
Epidural Injections: Lumbar
Epidural Injections: Lumbar
Epidural Injections: ODG

- Recommended as an option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy)
- Not recommended for spinal stenosis or for nonspecific low back pain
- Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing
- Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance
Epidural Injections: ODG

- Diagnostic vs. therapeutic
- Transforaminal, i.e. selective nerve root blocks vs. interlaminar approach
- No more than two nerve root levels should be injected using transforaminal injections
- No more than one interlaminar level
- No more than one to two injections during diagnostic phase
- Repeat injection not indicated if inadequate (<30%) response to initial injection unless inaccurate placement or multilevel pathology
Epidural Injections: ODG

- **Therapeutic phase:** If after the initial block/blocks are given and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported.
- Routine “series of three” not recommended.
- The general consensus recommendation is for no more than 4 blocks per region per year.
- Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.
Epidural Injections: ODG

- It is not recommended to perform epidural blocks on the same day as facet blocks, sacroiliac blocks, lumbar sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.
- Cervical and lumbar epidural steroid injection should not be performed on the same day.
- Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms.
Facet Joint Procedures: Lumbar
Facet Joint Procedures: ODG

- **Intra-articular Injections:**
  - Current evidence is conflicting as to this procedure
  - No more than one therapeutic intra-articular block is recommended
  - There should be no evidence of radicular pain, spinal stenosis, or previous fusion
  - If successful (initial pain relief of 70%, plus pain relief of at least 50% for a duration of at least 6 weeks), the recommendation is to proceed to MBB and subsequent neurotomy (if the MBB is positive)
Facet Joint Procedures: ODG

- Intra-articular Injections, cont’d:
  - No more than 2 joint levels should be blocked at any one time
  - There should be evidence of a formal plan of additional evidence-based activity and exercise in addition to facet joint injection therapy
Facet Joint Procedures: ODG

- Medial Branch Blocks (MBB)
  - Procedure is diagnostic, NOT therapeutic
  - One set of diagnostic MBB is required with a response of $\geq 70\%$. The pain response should last at least 2 hours for Lidocaine
  - Limited to patients with low-back pain that is non-radicular and at no more than two levels bilaterally
  - There is documentation of failure of conservative treatment (including home exercise, PT and NSAIDs) prior to the procedure for at least 4-6 weeks
Facet Joint Procedures: ODG

- Medial Branch Blocks, cont’d
  - No more than 2 facet joint levels are injected in one session
  - Recommended volume of no more than 0.5 cc of injectate is given at each level
  - No pain medication from home should be taken for at least 4 hours prior to the MBB and for 4 to 6 hours afterward
  - The use of IV sedation may be grounds to negate the results of MBB, and should only be given in cases of extreme anxiety
Facet Joint Procedures: ODG

- Medial Branch Blocks, cont’d
  - The patient should document pain relief with an instrument such as a VAS scale, emphasizing the importance of recording the maximum pain relief and maximum duration of relief
  - The patient should also keep medication use and activity logs to support subjective reports of better pain control
  - MBB should not be performed in patients who have had a previous fusion procedure at the planned injection level
Facet Joint Radiofrequency Neurotomy (RFA): Lumbar

- “Under Study”
- 3 RCTs with one suggesting reduced pain with potential to reduce narcotic requirements
- Trial analysis complicated by methodologic inconsistencies
- Systematic review that included several new observational studies came to the conclusion that the evidence for neurotomy was moderate (Level III) for long-term relief (Boswell et al, 2007)
Facet Joint Radiofrequency Neurotomy (RFA): Lumbar

- Treatment requires a diagnosis of facet joint pain based on positive response to MBB
- Repeat neurotomies should not occur at an interval of less than 6 months from the first procedure.
- Should not be repeated unless duration of relief for at least 12 weeks at $\geq 50\%$ relief.
- The current literature does not support that the procedure is successful without sustained pain relief (generally of at least 6 months duration).
- No more than 3 procedures should be performed in a year’s time.
Facet Joint Radiofrequency Neurotomy (RFA): Lumbar

- Approval of repeat neurotomies requires documented improvement in VAS score, decreased medications and documented improvement in function
- No more than two joint levels are to be performed at one time
- There should be evidence of a formal plan of additional evidence-based conservative care in addition to facet joint therapy
Sacroiliac Joint (SIJ) Blocks
Sacroiliac Joint (SIJ) Blocks: ODG

- Recommended as an option if failed at least 4-6 weeks of aggressive conservative therapy
- The history and physical should support the diagnosis
  - i.e. appropriate pain with positive clinical tests
- The patient has had and failed at least 4-6 weeks of aggressive conservative therapy including PT, home exercise and medication management
- Blocks are performed under fluoroscopy (or ultrasound)
- A positive diagnostic response is recorded as 80% for the duration of the local anesthetic
If steroids are injected during the initial injection, the duration of pain relief should be at least 6 weeks with at least > 70% pain relief recorded for this period.

The suggested frequency for repeat blocks is 2 months or longer between each injection, provided that at least >70% pain relief is obtained for 6 weeks.

Not to be combined with ESI, facet or MBB.

Maximum of 4 times for local anesthetic and steroid blocks over a period of 1 year.
Trigger Point Injections (TPIs)
Trigger Point Injections
Trigger Point Injections: ODG

- Must meet diagnostic criteria for myofascial pain syndrome (MPS)
  - Circumscribed trigger points, palpable twitch response (on injection), >3 month duration, failure of conservative care
- Radiculopathy not an indication but may be given if both radiculopathy and MPS are present together
- No more than 3-4 injections per session
- No repeat injections unless >50% pain relief with decreased medications and increased function documented
Trigger Point Injections: ODG

- Frequency should not be greater than every two months
- Should not include anything other than local anesthetic w/ or w/o steroid
- There should be evidence of continued ongoing conservative treatment including home exercise and stretching. NOT as sole treatment
- Reconsider if pain persists after 2-3 procedures
Sympathetic Blocks: ODG

- Used in the work-up and management of complex regional pain syndrome (CRPS)
- There should be evidence that all other diagnoses have been ruled out before consideration of use
- There should be evidence of successful sympathetic blockade with increased skin temp >1.5°C without sensory block
- Horner’s should be documented
- Generally given in rapid succession during first 2 weeks of treatment, tapering to weekly
- Continuing beyond 2-3 weeks is unusual
Sympathetic Blocks: ODG

- Use in *treatment* only recommended if favorable response to diagnostic block and documented improvement in motion, pain, activity tolerance, etc.
- PT/OT should be incorporated
- May be repeated for acute exacerbations
- Other treatments including psychological, pharmacological and rehabilitative should take place
- Sympathectomy and IV regional sympathetic blocks are not recommended due to lack of evidence and high complication rate
Piriformis Injections

Piriformis syndrome

Obturator internus

Sciatic nerve

Piriformis
Piriformis Syndrome: ODG

- “Piriformis syndrome is a common cause of low back pain and accounts for 6-8% of patients presenting with buttock pain, which may variably be associated with sciatica, due to a compression of the sciatic nerve by the piriformis muscle” - ODG
- Piriformis injections are recommended for piriformis syndrome after a one month physical therapy trial
Piriformis Injections
Spinal Cord Stimulation (SCS)
Spinal Cord Stimulation: ODG

- Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated
- There is evidence supporting the use of SCS for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions including CRPS
- In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy
The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure.

A trial of SCS is considered an indispensable step in determination of candidacy for permanent implant.

Over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to conventional medical management (CMM) for FBSS.

Psychological screening is recommended prior to all SCS implants.
Implantable Drug Delivery (IDDS)
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- Indications for non-cancer pain:
  - All non-opioid medications have been tried unsuccessfully
  - At least 6 months of other more conservative treatments have failed
  - Intractable pain with objective pathology
  - Further surgery or other treatment not indicated
  - Independent psych eval confirms pain not psychogenic and patient has realistic expectations
  - Documented improvement in pain and function with oral opioids but with intolerable side effects
  - Successful trial with at least 50% to 70% reduction in pain with improved function and decreased oral pain med use
“Unconventional” Therapies
Acupuncture
Acupuncture

- No particular acupuncture procedure found to be superior
- Mode of action not completely understood
- RCTs difficult to perform due to sham creating similar results as actual treatment
- Acupuncture traditionally defined as insertion of needles at specific points called acupuncture points
- Dry needling is distinct from acupuncture in that needles are inserted into myofascial trigger points
Acupuncture: ODG

- Recommended as an option for some conditions in conjunction with other interventions
  - Low back: Not recommended for acute LBP, but as an option in chronic LBP for short course of treatment
  - Head: Recommended for headaches, with better results in migraine than tension HA
  - Knee: Recommended for OA
  - Hip: Recommended for OA
  - Neck and upper back: Under study for upper back, not recommended for neck
  - Shoulder: Recommended as option in RC tendinitis
  - CTS: Not recommended
Acupuncture: ODG

- Initial trial of 3-4 visits over two weeks
- With evidence of reduced pain, medication use and objective functional improvement, total of up to 8-12 visits over 4-6 weeks
- The evidence is inconclusive for repeating this procedure beyond an initial short course of therapy.
“Regenerative” Medicine
Prolotherapy/Sclerotherapy

- Intent is to cause tissue irritation by injecting an agent such as hyperosmolar dextrose into soft tissue.
- Belief is that doing so will stimulate the production of new cells to strengthen weak connective tissues.
- A form of “regenerative medicine”
- Not recommended for the treatment of chronic pain.
- No proven value via well-controlled, double blind studies.
- May have harmful effects.
Stem Cell Autologous Transplantation

- Under study for advanced degenerative joint disease, rheumatoid arthritis, autoimmune disorders, diabetes, MS
- Uncertainty regarding best stem cell type and origin, dosage, timing, etc.
- Theoretical concern regarding potential carcinogenic effects
- Remains experimental and should be limited to RCTs
Platelet-Rich Plasma (PRP)

- Not recommended for chronic pain except in research setting
- Recent higher quality evidence showing no better than placebo for ankle disorders
- Under study for elbow, hip and knee disorders
- Not recommended for low back pain
Intradiscal Procedures
Intradiscal Electrothermal Annuloplasty (IDET)

- Involves placement of a navigable catheter posterolaterally into the disc
- Indirect RF energy then heats the disc to 90°C for up to 20 minutes
- Not recommended by ODG
- APS: Insufficient literature to support procedure
- Procedure NOT innocuous
  - Risks include discitis, epidural abscess, vertebral osteomyelitis, bacterial meningitis, nerve root damage, acute disc herniation and acceleration of DDD
Intradiscal Electrothermal Annuloplasty (IDET)
Nucleoplasty (Coblation)

- Uses bipolar RF energy to ablate nucleus of disc with low temperature plasma field of ionized particles
- Not recommended due to lack of clinical trials and extremely low level of evidence
- CMS recently issued a national noncoverage determination for all thermal intradiscal procedures (TIPs), including radiofrequency annuloplasty (RA) and percutaneous (or plasma) disc decompression (PDD) or coblation, concluding that a thorough review of the empirical evidence on TIPs is adequate to determine that there is no convincing evidence to demonstrate a benefit to health outcomes from these procedures
Nucleoplasty (Coblation)
Percutaneous Epidural Adhesiolysis (Racz Catheter Procedure)

- Not recommended due to lack of sufficient literature evidence
- Large variability in technique and technical ability of physician
- Potential adverse effects include dural puncture, spinal cord compression, hematoma, infection
- One recent RCT found reduction in VAS score compared with CMM group
Botulinum Toxin (Botox, Myobloc)
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- Great for wrinkles
- Not recommended for most chronic pain conditions
- Studies have found no statistical support for use in tension-type headache; fibromyalgia; chronic neck pain; myofascial pain syndrome (MPS)
- No better than saline in myofascial pain
- Useful in managing spasticity in SCI, TBI and other upper motor unit diseases
- Useful in migraine when other less invasive treatments have failed
Thank You