Evidence-Based Chronic Pain Guidelines

Patient Safety, Clinical Outcomes, & Reimbursements
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No XRays Needed Here

"Wait a minute here, Mr. Crumbley... Maybe it Isn't kidney stones after all."

Disclosure

✔ I do not have significant conflict of interest in medical commercial or private investment that is relevant to this presentation

✔ I will not name commercial medical corporations or companies by name

✔ I am not a board member of a commercial medical device or other medical company
Evidence-Based Guidelines


American Pain Society


- Review of 3348 abstracts, 161 RCT’s going back to 1970’s

- Goals included evidence-based recommendations for above

Purpose of Evidence-Based Guidelines in Chronic Pain Interventional Therapy

- Validate and optimize effective pain treatments
- Identify valuable allied multimodality therapies
- Improve functional and psychological capabilities and activities of daily living
- Improve Quality of Life
- Minimize adverse outcomes
Evidence-Based Medicine (EBM)

EBM: “the application of scientific method in determining optimal management of the individual patient” – Daly, 1990

Goal = to apply best evidence available from approved scientific methodologies to medical scientific and clinical decision-making

Medical Guideline

- A document which guides decisions and may implement criteria for the diagnosis, management, and treatment of areas of healthcare.
- Examples:
  - US: Agency for Healthcare Research and Quality
  - Great Britain: National Institute for Health and Clinical Excellence (NICE)

ASA 2010 Chronic Pain Guidelines

Seven –step process

1. Establish criteria for evidence
2. Collect original published peer-reviewed research
3. Expert consultants review opinion surveys and review draft guidelines
4. Solicit opinions on draft - ASA/ASRA
5. Task Force forums held at two national meetings WIP 5th World Congress and the APS– 2009
6. Consultants assess opinions on feasibility of the guidelines
7. All available information used to build consensus to finalize the guidelines

Guidelines completed!
Literature Reviews and Levels of Evidence

- Types of studies:
  - Randomized controlled studies
  - Observational studies
  - Case reports

- Types of literature:
  - Suggestive Literature
  - Equivocal Literature
  - Insufficient Evidence from the Literature

- Four Categories of Support A,B,C,D
  - Within each, 2 to 3 levels of support

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Literature Reviews and Levels of Evidence- for Category A

- Randomized Control Study p<0.01
- Supportive Literature with multiple RCT’s showing significant differences and findings supported by meta-analysis
- Level 2- Non-comparative observational studies with associated statistics
- Level 3- Literature contains case reports

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First Randomized Controlled Trial

- 1948—Efficacy of Streptomycin in treatment of tuberculosis

- 1990’s—Journal Evidence-Based Medicine

- Cochrane—British epidemiologist, used RCT in assessment of medical technologies and practices in 1950-1960’s and resulted in Cochrane Collaboration
Literature Reviews and Levels of Evidence- for Category B

• Suggestive Literature - Inference of benefit or harmful relationships among clinical interventions and outcomes

  • Level 1 - Observational comparison
  • Level 2 - Noncomparative observational studies
  • Level 3 - Literature contains case reports

Literature Reviews and Levels of Evidence- for Category C

• Equivocal Literature

  • Level 1 - Meta-analysis - no significant differences among groups or conditions
  • Level 2 - Insufficient number of studies to conduct meta-analysis
  • Level 3 - Observational studies report inconsistent findings—cannot infer benefits or harms

Tenets of Clinical Practice Guidelines

* Appraisal of quality of relevant evidence
* Comparison of benefits & harms of clinical recommendations
* Value judgments of these benefits and harms
* Quality of evidence as it relates to strength of recommendation
Literature Reviews and Levels of Evidence-for Category D

- Insufficient Evidence from Literature
- Studies do not identify relationships between interventions and outcomes
- Available literature cannot be used to assess relationships between interventions and outcomes

ASA 2010 Key Guideline Findings (1 of 2)

- History and Physical Examination are essential tools
- Sensory/Affective Pain Components
- Causes and effects of the pain
- Physical deconditioning
- Occupational status
- Psychosocial dysfunction

ASA 2010 Key Guideline Findings (2 of 2)

- Psychosocial Evaluation is important
- Identify anxiety, depression, anger
- Psychiatric disorders, personality traits
- Activities of Daily Living assessment
- Influence of pain on mood
- Ability to sleep, addictive/aberrant behaviors, interpersonal relationships
Multidisciplinary Programs

• May reduce the intensity of pain reported from four months to one year. (A2)
• Represent multi-modality approaches in context of a treatment program that includes more than one discipline
• Examples—anesthesiology, pain medicine, physiatry, neurology, neurosurgery, orthopaedics, rheumatology, psychiatry, psychology

Single-Modality Interventions

- Ablation
- Acupuncture
- "Blocks"
- Botulinum
- Electrical stimulation
- Epidural steroid injections
- Intrathecal drug delivery systems (IDDS)
- Minimally-invasive spine procedures
- Pharmacologic management
- Physical/restorative therapies
- Psychological therapies
- Trigger point injections

Evidence for Spinal Steroid Injections for Low Back/Leg Pain

• RCT of epidural interlaminar steroid injection:
  - Reduced pain scores at 6 months for leg pain (A3)
  - Equivocal for LBP (C2), when TF/ESI is compared with saline.
• RCT compared parasagittal interlaminar with the transforaminal approach, found:
  - Equivocal pain scores for LBP (C2)
Evidence for Spinal Steroid Injections for Low Back/Leg Pain

- **Shared decision-making** for ESI recommended
- **Discussion** of the complications, especially with the transforaminal approach
- **Image guidance**—performed for transforaminal lumbar injections, and considered for interlaminar injections

Evidence for Spinal Steroid Injections for Low Back/Leg Pain

- Epidural steroid w/ or w/o local anesthetics may provide from 2 wks - 3 mos. of LBP pain relief.
- Neck pain may be relieved for 1 wk. - 12 mos. (Level B2).
- Complications reported including dural puncture, infection, cauda equina syndrome discitis, neurologic deficits (B3)

Victory for Transforaminal ESI

- An exciting newer study:
  - 1st such study for lumbar radicular pain
  - 5-armed P-RCT of TF ESI (Ghahreman, Ferch and Bogduk, 2010)
- Significant results:
  - 54% of patients achieved >50% pain relief at 1 month; 25% at 6 months
  - 50% of patients avoided surgery, treatment was **less costly** over 2 years than surgical remedy (SCOPE)
- This is compared to:
  - 7% with LA, 19% with TFNS, 21% with IM steroids, and 13% with IM saline
Diagnostic Cervical Medial Branch Block Injection

- Results for cervical facet joint pain (B2) with medial branch blocks:
  - 54% sensitivity
  - 88% specificity
  - 81% positive predictive value
- RCT for facet joint injection showed:
  - *Equivocal* evidence for benefit (C2) vs. saline
  - B2 evidence for *improved pain* scores on observational studies for 1-6 mos.

Facet and Medial Branch Blocks

- RCT’s reveal:
  - *Equivocal* findings in the efficacy of facet steroid vs. saline injection (C2)
  - Improved pain scores for 1-6 months (B2)
- RCT – MBB and placebo control not found (D)
- Observational studies:
  - Improved pain control with MBB’s for 3-12 month with observational studies (B2)

Radiofrequency Rhizotomy

- Higher RF success rates
  - Controlled medial branch blocks
  - Local anesthetics of different durations are utilized at 6 months+
- Medial branch blocks can be repeated if lasting 3 months
- Successful RF rhizotomy expected to last 6-12 months
Diagnostic Sacroiliac Joint Injection

- Positive predictive value up to 72% for the identification of pain of sacroiliac origin
- Literature “insufficient” to evaluate efficacy of sacroiliac joint injection for pain relief (Category D)

Discography

- Provocative discography has 42-60% positive predictive value in identifying disc as a source of pain (B2)
- Should NOT be used for routine evaluation of a patient with chronic non-specific back pain
- Caution: discitis, epidural abscess, nucleus embolization, other complications (B3)

Sympathetic nerve blocks

- No studies were found looking at long-term efficacy of lumbar sympathetic or stellate ganglion blocks (D)
- 1 observational study of lumbar sympathetic blocks showed improvement in CRPS for one week (B2)
- Stellate blocks helped for 4 weeks in treatment of neuropathic (SMP) pain of CRPS (B3)
Peripheral Nerve Blocks

- Relief from pain for 1-14 days (B2)
- Diagnostic nerve blocks, peripheral or other, may help to determine:
  - Location of pain
  - Cause of pain (peripheral, central, psychogenic) (B2)
- This has been reported in studies with observational findings and case reports

Radiofrequency Ablation

- Lower Back Pain patients had lower pain scores for two to six months (A1)
- RCT of neck pain patients showed relief for up to six months (A3)
- Water-cooled RF (vs. sham controls) showed lower pain scores for three months (A3) for chronic SI joint pain
Electrical Nerve Stimulation

- TENS - Meta-analysis of RCT’s vs. sham controls reveals lower pain scores for:
  - 1 hr – 1 month for LBP (A1)
  - 3-6 months for other conditions (B3)
- SCS for CRPS shows 6-24 months of pain relief vs. physical therapy alone (A3)
  - Should be used for persistent radicular pain
  - ASA/ASRA members surveyed
  - B2 evidence for peripheral neuropathic pain including PHN
- Subcutaneous peripheral nerve stimulation show pain relief for 4-24 months (B2)

Minimally Invasive Spine Procedures

- Vertebroplasty, Kyphoplasty—RCT’s equivocal (C2) for patients with osteoporotic vertebral compression fx.
- Observational studies show effective pain relief (B2) for osteoporosis for 6-12 mos.
- Percutaneous disc decompression effective for 2 weeks to 12 months in relief of LBP with leg pain (B2)
Percutaneous Thermal Intradiscal Procedures

- **Insufficient evidence** to establish the efficacy of percutaneous thermal intradiscal procedures other than IDET—Category D evidence
- Pain scores were **improved however for 6-12 months** (B2).

Intrathecal Drug Delivery Systems

- Observational evidence that intrathecal opiates provide effective pain relief for 1-12 months (B2)
- Ziconotide can provide up to 48 hours of relief in patients with refractory neuropathic pain (B2)
- Intrathecal opiates may be used for patients with neuropathic pain

Intrathecal Drug Delivery Systems

- Intrathecal non-opioid ziconotide can be used in a "select subset" of patients with refractory chronic pain
- ASA and ASRA members are **equivocal** whether intrathecal opiates or infusion should be used for neuropathic pain
  - Trials should be done prior to permanent implantation
Acupuncture

- Meta-analysis for LBP established **C1 level of evidence for efficacy**
- Observational studies show one week to six months of **pain relief**

Botulinum Toxin

- Pyriformis syndrome A2 level of evidence efficacy with pain relief 8-12 weeks
- RCT of type A Botulinum toxin with saline placebo control showed only equivocal findings for myofascial pain.

Trigger Point Injections

- Literature is **insufficient** to evaluate efficacy for chronic pain patients (D)
- Membership recommends for myofascial pain relief
- Observational studies suggest **1 to 4 months of pain relief**
Pharmacologic Management

• Alpha-delta 2 calcium channel antagonists—effective pain relief for 5-12 weeks (A1)
• Meta-analysis of sodium channel antagonists or membrane stabilizing agents/anticonvulsants, pain relief 2-18 weeks (A1)
• A1 evidence for TCA’s 2-8 weeks, and for SNRI’s for variety of pain conditions via meta-analysis RCT’s

Pharmacologic management

• SSRI’s show only equivocal efficacy for diabetic neuropathy (placebo control)
• Benzodiazepines—B3 evidence for pain relief for up to two months
  – BUT consultants equivocal whether they should be used for chronic pain
• NMDA receptor antagonists—dextromethorphan, memantine

Pharmacologic Treatment

• Skeletal muscle relaxants—literature insufficient to evaluate efficacy (D)
• Topical agents—RCT’s, placebo-controlled, are equivocal (C2) for efficacy of:
  – Capsaicin
  – Lidocaine
  – Ketamine for peripheral neuropathic pain (diabetic neuropathy, PHN)
• Observational studies of topical agents show pain relief for 3 to 6 weeks (B2)
Pharmacologic management

- NMDA antagonists *equivocal* evidence only for diabetic neuropathy, PHN, other neuropathic pain (phantom limb)
- B2 evidence that NMDA receptor blockers may provide 2-16 weeks of pain relief
- NSAIDS—2-12 weeks of LBP relief in RCT’s with placebo controls (A2)

Pharmacologic Management with Opioids

- Meta-analysis of RCT’s—1 to 9 weeks of relief for LBP/neuropathic pain (A1)
- Tramadol—4-6 weeks of pain relief (A2)
- Observational studies reveal 2 weeks to 3 months of relief for immediate-release sublingual and transdermal opioid for LBP, neck, leg and neuropathic pain (B2)

Physical/Restorative Therapies

- Aquatic Conditioning and Exercise Program
- Progressive Desensitization to reduce pain
- Occupational therapies
- Goals of resolution of spontaneous pain to progression from passive to isometric & isotonic exercises
- There must be minimal pain
Physical and Restorative Therapies

- RCT’s show that fitness, exercises relieve LBP for 2 to 18 months (A2)!

Psychological/Cognitive Approaches

- Cognitive behavioral, biofeedback and relaxation training, supportive psychotherapy and counseling may relieve LBP for 4 weeks to 2 years (A2)
- Case reports suggest that supportive psychotherapy may assist in chronic pain management (B3)

Tenets of Clinical Practice Guidelines

- Appraisal of quality of relevant evidence
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Clinical Practice Guidelines We Can Trust

- Committee on Standards for Developing Trustworthy Clinical Practice Guidelines—Institute of Medicine, National Academies Press, Washington, D.C., 2011
- Funding for the study came from the Agency for Healthcare Research and Quality (AHRQ)

Institute of Medicine

- Established in 1970 by the National Academy of Sciences
- Examines policy matters pertaining to health of the public
- Adviser to the federal government to identify issues of medical care, research and education

Institute of Medicine

- Clinical Practice Guidelines (CPG)
- Evidence-Based Medicine
- Patient input into process of guideline development
- US Congress through the Medicare Improvements for Patients and Providers Act of 2008
- Request IOM study on best methods
Two Committees Formed

1. Committee on Standards for Systematic Reviews of Comparative Effectiveness
2. Committee on Standards for Developing Trustworthy Clinical Practice Guidelines

Ideal Clinical Practice Guidelines

- Systematic review
- Multidisciplinary panel of experts with representatives from key affected groups
- Consider subgroups and patient preferences
- Explicit and transparent processes
- Ratings of quality of evidence and strength of recommendations

Ideal Clinical Practice Guidelines

- Reconsideration and revision when appropriate
- Should be independent of the billions of dollars which channel health care through marketing and lobbying
- Should question the status quo and strive to improve patient health
**Patient & Public Input**

- Patients at high risk for atrial fibrillation placed (compared to physicians treating patients with atrial fibrillation):
  - **More value** on avoidance of stroke
  - **Less value** on avoidance of bleeding (Devereaux, et al, 2001)

- Where is the patient input in medical guidelines?

**Consumer Input in Guidelines**

- Guidelines not derived “behind closed doors,” enhances transparency
- New perspectives—that of the patient
- Safeguard against conflicts of interest

- NICE incorporates:
  - Patient involvement unit
  - Patient & caregiver representation
  - Patient focus groups
  - Written testimonials
  - Feedback process

**Electronic Health Record**

- Includes:
  - Clinical practice guidelines (CPG)
  - Adverse pharmaceutical medication interactions screens for risk assessment
  - Streamline procedural methodologies based upon selected CPGs utilized
- Focus on the patient in the equation
Reimbursement

- Medial Branch Blocks and Medial Branch Thermal Radiofrequency Neurotomy in Lumbar Facet Pain
- Noridian Administrative Services
- Proposed abolishment of reimbursement by Noridian on basis of faulty, invalid studies
- Value of controlled medial branch blocks

Proposed Non-Coverage by Noridian—2009

- Codes 64475, 64476, 64622, 64623
- Based on:
  - Invalid techniques published in reviewed articles as references
  - Billings by primarily non-interventionalists, many of whom did not use fluoroscopy
  - Cumulative high charges for excessive levels performed and high frequency of performance

Collective Response to Noridian

- Measured and thoughtful response from many societies including:
  - American Academy of Pain Medicine
  - International Spinal Injection Society
  - American Academy of Orthopedic Surgeons
  - And others
- Call for rational and correct performance of procedures with controlled trial of medial branch blocks to the facet joints
Reimbursements

- Epidural steroid injections—should be done for patients with lower back AND radicular extremity pain
- Transforaminal (TF) injections generally associated with higher incidence of success in pain relief than dorsal interlaminar approach
- National moratorium called in performance of cervical TF injections (Rathmell)

Reimbursement—Spinal Cord Stimulation

- Spinal cord stimulation—One of the few procedures to see general increase in reimbursement from third party payers
- Efficacy well demonstrated for lower back and radicular pain, better than repeat surgeries
- Efficacy for complex regional pain syndrome, neuropathic pain, phantom limb pain, post-herpetic neuralgia