Updates to the ACOEM Occupational Medicine Practice Guidelines

Methodology
Low Back Complaints
Pain Management
Elbow Complaints

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Caveat Emptor

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The Goals of EBM in Occupational Medicine

- Reduce variance from best practices
- “[High] variance amounts to a roll of the dice in making health care decisions”
- Donald Berwick MD, CEO, Institute for Healthcare Improvement
- “Random treatment strategies create random outcomes. This... does not inspire confidence in medical care.”
- John Wennberg MD, Dartmouth School of Medicine
The ACOEM Methodology

Redesigned
More Explicit
Starting with Revised 2nd Edition


Why Is Methodology Important?

- The rigor of methodology is directly correlated with the reproducibility of the recommendations
- Critical appraisal and synthesis are critical steps
- Properly done panel processes have been shown to improve consistency and benefit:risk
- The ACOEM methodology is incorporated into the DWC regulations in California
- Guidelines should follow the methodology to maximize the probability of accuracy

The ACOEM Methodology

- Pose answerable clinical questions
- Person, intervention, comparison, outcome
- Formulate search strategy, terms
- Inclusion, exclusion criteria
- Electronic search
- Hand search
- Quality grading of studies
  - Vs categorization by study design
- Summarize (high quality) studies
  - Evaluation of heterogeneity of results
  - Synthesis meta-analysis of high-quality studies
- Grade the body of evidence
ACOEM Literature Search

Exhaustive Searches for Randomized Controlled Trials (RCTs):
- The National Library of Medicine’s MEDLARS database (Medline)
- The Cochrane Central Register of Controlled Trials
- TRIP Database
- CINAHL (Nursing, allied health, physical therapy, occupational therapy, social services)
- EMBASE
- PEDro: Physiotherapy Evidence Database

The ACOEM Methodology

- Formulate draft recommendations
- Panel review and approval of grading, summaries, draft recommendations
- Balance risks and benefits, consider resource allocation
- Gaps in evidence filled by structured clinical consensus
- Apply First Principles
- Editing, revision
- Methodological and editorial review
- External review
- Pilot testing
- Board review
- Cyclical repeat of the process

Study Design Level: Treatment

1a. Individual high-quality randomized controlled trial with narrow confidence interval
1b. All or none studies
2. High quality individual cohort studies or lower quality RCTs
3a. High quality individual case-control studies
3b. High quality retrospective cohort studies
4. Case series
   - Poor quality cohort studies
   - Poor quality case-control studies
   - Expert opinion without explicit critical appraisal
   - Expert opinion based on physiology, bench research, “first principles”.
Study Design Level: Assessment

1a. Independent blind comparison of patients from an appropriate spectrum of patients, all undergoing the diagnostic test and reference standard
1b. Clinical Practice Guideline validated on a test set
1c. Absolute SpPins and SnNouts

2a. Independent blind or objective comparison study of non-consecutive patients, or narrow spectrum, all undergoing the diagnostic test and reference standard
2b. Diagnostic CPG not validated on a test set

3. Independent or blind comparison of an appropriate spectrum but the reference standard was not applied to all patients

4. Case series
   - Poor quality cohort studies
   - Poor quality case control studies
   - Expert opinion without explicit critical appraisal
   - Expert opinion based on physiology, bench research, "first principles"

The ACOEM Guideline Process Does Not Consider as Evidence:
- Case studies of individual patients or non-controlled groups of patients
- Reports and literature from industry
- Studies that are not peer-reviewed
- Studies with undisclosed conflicts of interest
- Other guidelines
Evidence Evaluation Caveats

From the School of Hard Knocks

- Evidence searches
  - CAVEAT: Many studies are not listed in PubMed
    - Search other databases, hand searches mandatory
- Ranking studies by design
  - CAVEAT: Many abstracts and PubMed incorrectly label studies
  - CAVEAT: Design is NOT the same as methodological quality or reproducibility
- Assess SR/MA quality
  - CAVEAT: Many SRs and MAs are not systematic or critical
    - Cochrane reviews usually the exception;
    - Many done by non-clinicians

Evidence Grading for Treatment

- Randomization
- Treatment allocation concealed
- Baseline Comparability
- Patient blinded
- Provider blinded
- Assessor blinded
- Controlled for co-interventions
- Compliance acceptable
- Dropout rate
- Timing of Assessments
- Analyzed by intention to treat,

Scoring scale = 0, 0.5, 1

Grading the Body of Evidence

- A - Strong evidence-base: Two or more high-quality studies.
- B - Moderate evidence-base: At least one high-quality study, or multiple lower-quality studies relevant to the topic and the working population.
- C - Limited evidence-base: At least one study of intermediate quality.
- I - Insufficient Evidence: Evidence is insufficient or irreconcilable.

Grading the Body of Evidence

- A - Strong evidence-base: Two or more high-quality studies.
- B - Moderate evidence-base: At least one high-quality study, or multiple lower-quality studies relevant to the topic and the working population.
- C - Limited evidence-base: At least one study of intermediate quality.
- I - Insufficient Evidence: Evidence is insufficient or irreconcilable.

For therapy and prevention, randomized controlled trials (RCTs) with narrow confidence intervals and minimal heterogeneity.

For diagnosis and screening, cross sectional studies using independent gold standards.

For prognosis, etiology or harms, prospective cohort studies with minimal heterogeneity.

For therapy and prevention, well-conducted cohort studies.

For prognosis, etiology or harms, well-conducted retrospective cohort studies or untreated control arms of RCTs.
Recommendation Levels

- **Strongly Recommended (A)**
  - The intervention is strongly recommended for appropriate patients. The intervention improves important health and functional outcomes based on high quality evidence, and the Evidence-Based Practice Panel (EBPP) concludes that benefits substantially outweigh harms and costs.

- **Moderately Recommended (B)**
  - The intervention is recommended for appropriate patients. The intervention improves important health and functional outcomes based on intermediate quality evidence that benefits substantially outweigh harms and costs.

- **Recommended (C)**
  - The intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional abilities.

- **Insufficient – Recommended (Consensus-based) I**
  - The intervention is recommended for appropriate patients and has nominal costs and essentially no potential for harm. The EBPP feels that the intervention constitutes best medical practice to acquire or provide information in order to best diagnose and treat a health condition and restore function in an expeditious manner.

- **Insufficient-No Recommendation (Consensus-based) I**
  - The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP feels that the intervention is ineffective, or that harms or costs outweigh benefits.

- **Strongly Not Recommended (A)**
  - Strong recommendation against providing the intervention to eligible patients. The EBPP found high quality evidence that the intervention is ineffective, or that harms or costs outweigh benefits.

- **Moderately Not Recommended (B)**
  - Recommendation against routinely providing the intervention to eligible patients. The EBPP found at least intermediate evidence that the intervention is ineffective, or that harms or costs outweigh benefits.

- **Not Recommended (C)**
  - Recommendation against routinely providing the intervention. The EBPP found at least intermediate evidence that harms and costs exceed benefits based on limited evidence.

- **Insufficient – Not Recommended (Consensus-based) I**
  - Insufficient evidence for an evidence-based recommendation that the intervention is not recommended for appropriate patients because of high costs/high potential for harm to the patient.

- **Insufficient – Not Recommended (Consensus-based) I**
  - Insufficient evidence for an evidence-based recommendation that the intervention is not recommended for appropriate patients because of high costs/high potential for harm to the patient.

- **Insufficient-No Recommendation (Consensus-based) I**
  - Insufficient evidence for an evidence-based recommendation that the intervention is not recommended for appropriate patients because of high costs/high potential for harm to the patient.

- **Insufficient-No Recommendation (Consensus-based) I**
  - Insufficient evidence for an evidence-based recommendation that the intervention is not recommended for appropriate patients because of high costs/high potential for harm to the patient.
Low Back Complaints

With Added Recommendations for CRPS, Neuropathic Pain, Trigger Points/Myofascial Pain, and Chronic Persistent Pain

Chronic Nonspecific Low Back Pain

- LBP lasting longer than 3 months (12 weeks) is defined in this document as “chronic.”
- Chronic LBP is labeled as “nonspecific” when it is deemed to be not attributable to a recognized, known specific pathology.¹
- The vast majority of chronic LBP is nonspecific
- Imaging does not equal causation of complaints


Diagnostic Studies

<table>
<thead>
<tr>
<th>Test</th>
<th>Indication</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plain X-rays</td>
<td>Red flags</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Subacute, chronic</td>
<td></td>
</tr>
<tr>
<td>Flexion/extension</td>
<td>Symptomatic spondylolisthesis</td>
<td>I</td>
</tr>
<tr>
<td>MRI</td>
<td>Red flags</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Radic &gt; 4-6 wks</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Select chronic</td>
<td>I</td>
</tr>
<tr>
<td>CT</td>
<td>Subacute</td>
<td>C</td>
</tr>
<tr>
<td>Myelography</td>
<td>Unusual, specific</td>
<td>I</td>
</tr>
<tr>
<td>ENG/NCV</td>
<td>Equivocal MRI/CT, ongoing</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>radicular pain</td>
<td></td>
</tr>
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</table>
### Diagnostic Studies

<table>
<thead>
<tr>
<th>Test</th>
<th>Indication</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>NOT LBP</td>
<td>I</td>
</tr>
<tr>
<td>Bone scan</td>
<td>CRPS &gt; 6 mo.</td>
<td>I</td>
</tr>
<tr>
<td>Discography</td>
<td>None</td>
<td>B</td>
</tr>
<tr>
<td>MRI discog.</td>
<td>None</td>
<td>C</td>
</tr>
<tr>
<td>Myeloscopy</td>
<td>None</td>
<td>I</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>None</td>
<td>I</td>
</tr>
<tr>
<td>SPECT</td>
<td>None</td>
<td>I</td>
</tr>
<tr>
<td>Standing/WB MRI</td>
<td>None</td>
<td>I</td>
</tr>
<tr>
<td>Thermography</td>
<td>None</td>
<td>I</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>NOT LBP</td>
<td>I</td>
</tr>
</tbody>
</table>

### Pharmacologic Treatment

#### TCAs
- CPP
- CLBP
- Radicular pain

#### SSRIs
- Fibromyalgia
- NOT CLBP

#### Opioids
- NOT routine use
- Select CPP
- Select CLBP
- Select neuropathy

#### 1 course of systemic glucocorticoids
- Acute severe radiculopathy
- NOT acute LBP

#### Muscle relaxants
- Severe acute LBP < 2 weeks
- CLBP (exacerbation only)
- CPP
- Neuropathic radic - 2nd

#### Gabapentin, pregabalin
- Neuropathic pain
- Perioperative
- Spinal stenosis
- Chronic radic
- NOT CLBP
**Active Treatment**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Indication</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic exercise</td>
<td>Acute, subacute, CLBP</td>
<td>A</td>
</tr>
<tr>
<td>Stretching</td>
<td>Acute, subacute, CLBP</td>
<td>C</td>
</tr>
<tr>
<td>Strengthening after aerobic</td>
<td>Acute, subacute, CLBP</td>
<td>C</td>
</tr>
</tbody>
</table>

**Exercise: Aerobic**

- **Recommended** for all patients, although most quality evidence is on chronic LBP (A). [CRPS (C), TP (I), CPP (A)]
  - Recommend a structured, progressive walking program.
  - Some controversy about bicycling (biomechanics: lordosis). Also, back muscles less active.
- No evidence on other specific exercises, but there is a direct correlation between benefit and the amount of aerobic activity that results in higher MET expenditure.
- **Prescribe what they will adhere to.**
  - Cardiac disease, or significant potential should consider pre-exercise evaluation (ACSM's Guidelines for Exercise Testing and Prescription (7th ed.))
- **Chronic LBP: Walking** at least 4x per week at 60% of predicted maximum heart rate (220-age=maximum heart rate). One successful study benchmarked 20 mins. during week 1, 30 mins. during week 2, 45 mins. after that point.
- **Acute or Subacute LBP: Graded** walking program, often with distance or time as minimum benchmarks. E.g., start with 10-15 mins. twice/day for 1 week, and increase in 10-15 min. increments per week until at least 30 mins./day is achieved.
  - **Strongly Recommended, Evidence (A)**
  - Aerobic exercise believed highly important for post-operative but no quality data.
  - **Recommended, Insufficient Evidence (I)**
Stretching and Flexibility

- **Acute LBP.** Specific stretching exercises are somewhat helpful for acute LBP. **Aerobic exercise should be first line treatment.**
- Either slump stretch-related exercises or directional preference stretching exercises are recommended.
- **Generic stretching exercises are not recommended. Evidence (C)**
- Stretching exercises as an isolated prescription or program for preventing LBP are not recommended.
- **NOT Recommended, Evidence (C)**

Strengthening and Stabilization Exercises

- Evidence of efficacy of aerobic exercises appears greater and should be initiated first.
- Develop home exercise program.
- Some may need supervised program (e.g., lacking motivation, or with fear avoidant beliefs).
- **Recommended, Evidence (C) [CPP (C), TP (I)]**
- Strengthening of abdominal muscles is a frequent goal.
- No quality evidence that these exercises are effective for treatment or prevention. Other treatment strategies have efficacy.
- **NOT Recommended, Insufficient Evidence (I)**
- Fear Avoidance Belief Training and principles appear important and should be incorporated.
- **Recommended, Insufficient Evidence (I)**

Passive Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Indication</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat</td>
<td>All LBP - self</td>
<td>C</td>
</tr>
<tr>
<td>Cold</td>
<td>Acute LBP - self</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>NOT high tech</td>
<td></td>
</tr>
<tr>
<td>Massage</td>
<td>CLBP - adjunct</td>
<td>C</td>
</tr>
<tr>
<td>Manipulation</td>
<td>Acute, subacute</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prediction rule</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>NOT pred rule</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>NOT CLBP</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>NOT radiculop</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>NOT neck</td>
<td>I</td>
</tr>
<tr>
<td>TENS</td>
<td>CLBP - adjunct</td>
<td>C</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>CLBP - adjunct</td>
<td>I</td>
</tr>
</tbody>
</table>
ACOEM Revised Recommendations - Chronic LBP

- Participatory ergonomic programs for highly select chronic LBP (C)
- Multidisciplinary rehabilitation program with a participatory ergonomics team for chronic LBP with lost-time injuries (C)
- Multidisciplinary rehabilitation programs with focus on cognitive behavioral, occupational, and activity-based approaches combined with aerobic exercise and other conditioning exercises (C)
- Cognitive behavioral therapy as a component of a formal interdisciplinary program (C)

ACOEM Revised Recommendations - Chronic LBP

- Work conditioning and work hardening programs (C)
- Trial of aquatic therapy (I)
- Patient meets referral criteria for supervised exercise therapy and co-morbidities that preclude participation in weight-bearing physical activity
- Inclusion of Fear Avoidance Belief Training during course of rehabilitation (I)

ACOEM Revised Recommendations - Chronic Radiculopathy

- Back school and education for chronic radicular pain syndromes (B)
- TENS for chronic radicular pain syndrome as an adjunct for more efficacious treatments (C)
- Massage for chronic radicular pain syndromes (I)
ACOEM Revised Recommendations – Spondylolisthesis

- Aerobic exercises (I)
- Strengthening and stabilization exercises after aerobic exercises instituted (I)
- Inclusion of Fear Avoidance Belief Training during course of rehabilitation (I)

*No evidence of work-relatedness

Lumbar Epidural Injections

- Option for acute or subacute radicular pain. Purpose is partial pain relief while awaiting spontaneous improvement.
- Pain at least 3 weeks treated with NSAIDs without evidence of trending towards spontaneous resolution.
- Evaluate after each injection. NO "series of 3."
- Second injection optional for partial responders who worsen and not interested in surgery. Recommended, Insufficient Evidence (I)

Lumbar Epidural Injections

- Option for second line treatment for spinal stenosis flares (less robust evidence).
  - Recommended each injection be scheduled, and effects of each injection be evaluated before additional injections, rather than scheduling a "series of 3."
  - Resolution of the symptoms of spinal stenosis, or decrease in symptoms to a "tolerable" level.
  - Recommended, Insufficient Evidence (I)
Lumbar Epidural Injections

- Epidural glucocorticosteroid injections are not recommended for acute, subacute or chronic LBP in the absence of significant radicular symptoms. They are also not recommended as first or second line treatment in individuals with LBP symptoms that predominate over leg pain. They are not recommended as treatment for any chronic problem.
- NOT Recommended, Evidence (C)

Tender and Trigger Point Injections

- 4 high-and moderate-quality RCTs
- Trigger and/or tender point injections are not recommended for acute LBP.
- NOT Recommended, Insufficient Evidence (I)
- Trigger or tender point injections may be reasonable secondary/tertiary options for subacute or chronic LBP not resolving.
- Should consist solely of a topical anesthetic (e.g., bupivacaine). (Dry needling?)

- Repeated injections linked to subjective AND objective improvements.
- Use of therapeutic injections without participation in active therapy program or a context of maintaining employment is not recommended.
- Alternative option is acupuncture.
- Recommended to allow at least 3-4 weeks between injections. If results not satisfactory after the first set of injections, a second set is reasonable. If not subjective AND objective improvements, further injections not recommended.
- Recommended, Evidence (C)
Diagnostic Facet Joint Injections (Intraarticular and Nerve Blocks)

- 4 moderate-quality RCTs
- **One diagnostic facet joint injection may be recommended** for patients with chronic LBP that is:
  - significantly exacerbated by extension and rotation or associated with lumbar rigidity, and
  - not alleviated with other conservative treatments (e.g., NSAID, aerobic exercise, other exercise, manipulation) in order to determine whether specific interventions targeting the facet joint are recommended.

Repeated diagnostic injections in the same location(s) are not recommended.

**No Recommendation, Insufficient Evidence (I)**

Therapeutic Facet Joint Injections

- 5 high-and moderate-quality RCTs
- Therapeutic facet joint injections are not recommended for acute, subacute, or chronic low back pain, or for any radicular pain syndrome.
- **NOT Recommended, Insufficient Evidence (I)**
Radiofrequency Neurotomy, Neurotomy, and Facet Rhizotomy

- 8 high- and moderate-quality RCTs
- Radiofrequency neurotomy, Neurotomy, and Facet Rhizotomy are not recommended for the treatment of any spinal condition.
- NOT Recommended, Evidence (C)

Discectomy, Microdiscectomy, Sequestrectomy and Endoscopic Decompression

- 16 moderate-quality RCTs or quasi-RCTs
- Lumbar discectomy recommended with radiculopathy and functional limitation after 4-6 weeks and appropriate conservative therapy.
- Should inform patients “there is evidence that there is no need to rush surgical decisions as there is no difference in long term functional recovery whether the surgery is performed early or delayed.”

- Open disectomy, microdiscectomy, and endoscopic discectomy are all potentially appropriate. Decision up to surgeon and patient until quality evidence available.
- Percutaneous discectomy (nucleoplasty), laser discectomy, and disc coblation therapy are not recommended for any back or radicular pain syndrome.
- Moderately NOT Recommended, Evidence (B)
Discectomy, Microdiscectomy, Sequestrectomy and Endoscopic Decompression

- Indications (all):
  - Radicular pain with current dermatomal pain and/or numbness, or myotomal muscle weakness all consistent with herniated disc
  - Imaging findings by MRI, or CT with/out myelography that confirm persisting nerve root compression at same level and side predicted by history and examination
  - Continued significant pain and functional limitation after 4-6 weeks of time and conservative therapy
  - Moderately Recommended, Evidence (B)

Fusion

- Lumbar fusion is recommended for isthmic spondylolisthesis.
  - Recommended, Evidence (C)
- Degenerative spondylolisthesis: Lumbar fusion is recommended
  - Recommended, Evidence (C)
- Stenosis without instability
  - Not recommended (C)
- CLBP
  - Moderately NOT Recommended (B)

Implantable Spinal Cord Stimulators

- No quality evidence for longer term treatment of chronic LBP with or without lower extremity pain.
- Data from an RCT on CRPS look similar and fail to show statistical benefit at 3-5 years.
- Other treatment options for chronic LBP have demonstrated efficacy.
- NOT Recommended, Insufficient Evidence (I)
Acupuncture

- 18 high- and moderate-quality RCTs
- Acute, Subacute or Radicular LBP: No quality evidence – other treatments are efficacious.
  - NOT Recommended, Insufficient Evidence (I)
- Chronic LBP: Select use recommended as an adjunct to more efficacious treatments
  - Should have clear objective and functional goals to be achieved.
  - E.g., adjunct to a conditioning program that has both graded aerobic exercise and strengthening exercises.
  - Not recommended for those not involved in a conditioning program, or who are non-compliant with graded increases in activity levels (C).

Low Back Pain in a Mechanic

- 35 year old mechanic lifted transmission at work 2 days ago
- Pain in low back to knees
- Tender to palpation over LS spine
- Former weight lifter and semi-pro football player
- No incontinence
- Off work

Formulate an Initial Treatment Plan for Joe Lobach

- What diagnostic testing would you suggest?
- What pharmacologic treatment would you recommend?
- What physical therapy would you order?
- What activity modifications would you suggest?
- Would you suggest any procedures?
Low Back Pain in a Mechanic

2 months later...
- Mr. Lobach reports persistent low back pain with occasional “excruciating” zingers to both legs
- He states SLRs make his back hurt at 70 degrees
- Gait is antalgic, moves slowly
- Reflexes, sensory and motor of legs normal
- Patient is off work
  - Dislikes boss
  - Disputes with wife
  - 2 brothers and mother are disabled
  - Seems to be doing ADLs
  - Drove to last appointment

Formulate a Revised Treatment Plan for Joe Lobach
- What diagnostic testing would you suggest?
- What pharmacologic treatment would you recommend?
- What physical therapy would you order?
- What activity modifications would you suggest?
- Would you suggest any procedures?

Low Back Pain in a Mechanic

DOI 2 years ago
- Persistent low back pain
- Functional status – not working
- Comorbidity
  - Obesity, no exercise, diabetes
  - Depressed
- Yellow flags
  - Wife supports him
  - Family history of chronic pain
- MMPI results show some dependent tendencies
- Number of prior PT treatments – 50
Formulate a Revised Treatment Plan for Joe Lobach at this point

- What diagnostic testing would you suggest?
- What pharmacologic treatment would you recommend?
- What physical therapy would you order?
- What activity modifications would you suggest?
- Would you suggest any procedures?

ACOEM Revised Recommendations: Epicondylalgia/it is/tendinosis

- Recommended
  - Medications
    - Topical NSAIDs, oral NSAIDs (B)
    - Bupivacaine/corticosteroids (C)
    - Corticosteroid injections (B)
    - Acetaminophen, aspirin (I)
    - Opioids - severe, acute (I)
  - Procedures
    - Surgery (type?) after at least 6 months of failed conservative treatment (I)
    - 3 months in “unusual circumstances” (I)

- Not recommended
  - Medications
    - Opioids (I)
    - Autologous blood injections (I)

ACOEM Revised Recommendations: Epicondylalgia/it is/tendinosis

- Recommended
  - Physical methods
    - Ultrasound (B)
    - Iontophoresis (C)
    - Heat or cold packs (I)
    - Home exercise (I)
    - Activity modification (I)
    - Epicondylalgia supports (I)
    - Workstation modifications (I)
    - Acupuncture (I)

- Not recommended
  - Physical methods
    - Extracorporeal shock wave therapy (A)
    - Low level laser (A)
    - Phonophoresis (C)