Interventions to Improve the Management of Chronic Back Pain—The Primary Care Perspective

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Midwest Pain Society
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Objectives

• To describe a stepped-care approach to manage chronic back pain (CBP)
• To identify specific tasks a pain care manager may play in treating CBP
• To describe algorithm-based analgesic management of CBP

Disclosures

• I have no relevant financial disclosures to make
• I will not discuss any off-label, experimental, or investigative use of drugs or devices in this presentation
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Managing Pain in Primary Care: Issues and Challenges

Evaluation of Stepped CAre for Chronic Pain (ESCAPE) in Iraq and Afghanistan Veterans: A Randomized Trial

Funding source: VA Rehabilitation Research & Development Merit Review No: F44371


Chronic Pain: A critical problem among Veterans

• Most symptom reported in PGW vets (Kroenke et al., 1999)
• 40% to 50% OEF/OIF veterans reported persistent pain (Clark, 2004; Gironda et al., 2006)
Evidence gap

- Prevalent and substantial functional, psychological, and economic impact
- Few studies address chronic pain
- No studies in recent veterans

Study Objective

- To determine if a stepped-care intervention is more effective than usual care in reducing:
  - Pain-related disability
  - Pain interference and pain severity
- In Iraq and Afghanistan veterans with chronic musculoskeletal pain

What is a Stepped-Care Intervention?

- Starting with lower intensity, less costly treatments (Step 1)
- “Stepping up” to more intensive, costly, or complex treatments
  - In patients that are “poor responders”
- Low Back Pain (Von Korff), PGW Syndrome (Engel)

ESCAPE Conceptual Model

<table>
<thead>
<tr>
<th>Care Intensity</th>
<th>Targeted Participants</th>
<th>Intervention</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1 (2 parts)</td>
<td>OF/OFF veterans with disabling musculoskeletal pain</td>
<td>Analgesics coupled w/ self-management strategies</td>
<td>Reduce pain intensity, Encourage activity, Provide education</td>
</tr>
<tr>
<td>Step 2</td>
<td>Veterans with persistent pain and disability at 12 weeks</td>
<td>Cognitive behavioral therapy</td>
<td>Identify difficulties, Reframe thoughts, Enhance coping</td>
</tr>
</tbody>
</table>

Eligibility Criteria: Inclusion

- Iraq and Afghanistan Veterans
- Chronic musculoskeletal pain (> 3 months)
  - Low back, cervical spine, or extremities (shoulder, hip, knee)
  - Moderate functional impairment defined as Roland Morris Disability Score ≥ 7
Main Outcomes

- **Pain related disability**
  - Roland Morris Disability Scale (24-items)
- **Pain Interference**
  - 7-item BPI Interference Scale (BPI) (Cleeland 1990)
- **Pain Severity**
  - Grade Chronic Pain Scale (CGPS) (von Korff, Swaen, & Li)

Intervention: Step 1

- **Steped-care model** (von Korff, 2001)
- **Analgesic use and optimization**
  - Evidence based algorithm (Kroenke, Krebs & Bair, Gen Hosp Psychiat, 2009)
  - Previous pain treatments assessed
  - Regular follow-up calls (q 2 weeks)
    - Assess response to treatment
    - Assess side effects and adherence
    - Desire for treatment change

Intervention: Step 1

- **Pain self-management strategies**
  - Pain education (natural history of pain)
  - Minimize bed rest
  - Stretching/strengthening exercises
  - “Menu” of strategies
    - Goal setting
    - Problem solving
    - Relaxation techniques
    - Communication with health care team

Analgesic Algorithm: Non-opioids

<table>
<thead>
<tr>
<th>Step</th>
<th>Analgesic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1 (Simple analgesics)</td>
<td>Acetaminophen, Naproxen</td>
</tr>
<tr>
<td>Step 2 (other NSAIDs)</td>
<td>Ibuprofen, Meloxicam, Etodolac, Diclofenac, Salsalate</td>
</tr>
<tr>
<td>Step 3 (Topicals, gabapentin, muscle relaxants, tramadol)</td>
<td>Capsaicin (topical), Gabapentin, Cyclobenzaprine, Tramadol</td>
</tr>
<tr>
<td>Step 4 (TCAs)</td>
<td>Nortriptyline, Amitriptyline</td>
</tr>
</tbody>
</table>

Analgesic Algorithm: Opioids

<table>
<thead>
<tr>
<th>Step</th>
<th>Analgesic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 5 (SA opioids)</td>
<td>Hydrocodone/acetaminophen, Oxycodone/acetaminophen</td>
</tr>
<tr>
<td>Step 6 (LA opioids)</td>
<td>Morphine SR, MorphineIR, Methadone</td>
</tr>
</tbody>
</table>

Stepped-Care Intervention: Step 1

- **Pain Self-Management Program** (Damush, Lorig)
  - Pain education
  - Physical Activity (return to normal activities)
  - Alternative thinking (goal setting)
  - Working with health care providers
  - Stress management (e.g. deep breathing)
**Intervention: Step 2**

Brief cognitive-behavioral therapy
- Adapted treatment manual (Davis, 2005; Lysaker, 2005)
- 6 individual sessions over the phone
- Identify maladaptive thoughts
- Inaccurate interpretations of pain and impact
- Supervised by study psychologist

**Intervention Delivery**

- Delivered by nurse case managers
- Weekly case management meetings

**Usual Care: Control Group**

- Educational handouts: musculoskeletal pain
- Recommended to seek treatment advice from PCP

**Sample characteristics (n=241)**

- Mean age: 36.7 (10.2)
- Sex: 88.4% men
- Married: 54.4%
- Race:
  - 76.8% White
  - 12.9% Black
- Income:
  - 36.5% comfortable
  - 18.7% NOT enough
- Military branch
  - Army: 66.4%
- Deployment:
  - Iraq: 74.9%
  - Afghanistan: 8.9%
  - Both: 16.3%
- Pain location:
  - Back: 57.3%
  - Knee: 21.6%
  - Neck: 7.5%
  - Shoulder: 7.1%
  - Hip: 6.6%

**Baseline Pain Measures**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Stepped-care Mean (SD)</th>
<th>Usual Care Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roland Disability</td>
<td>14.0 (4.3)</td>
<td>13.7 (4.7)</td>
<td>0.62</td>
</tr>
<tr>
<td>BPI-Interference</td>
<td>5.3 (2.1)</td>
<td>5.4 (2.4)</td>
<td>0.86</td>
</tr>
<tr>
<td>GCPS Pain Severity</td>
<td>67.3 (12.1)</td>
<td>65.1 (15.2)</td>
<td>0.22</td>
</tr>
</tbody>
</table>

**Between group difference: Pain Disability**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Stepped-care Mean (SD)</th>
<th>Usual Care Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Roland Disability</td>
<td>14.0 (4.3)</td>
<td>13.7 (4.7)</td>
<td>0.62</td>
</tr>
<tr>
<td>9-month Roland</td>
<td>10.6 (6.3)</td>
<td>12.1 (6.4)</td>
<td>0.075</td>
</tr>
<tr>
<td>Change</td>
<td>-3.7 (-4.5, -2.8)</td>
<td>-1.7 (-2.6, -0.9)</td>
<td>p=0.0024</td>
</tr>
</tbody>
</table>

Between group difference: 1.9 points 95% CI 3.2, -0.7
30% improvement

• Intervention group were more likely to demonstrate at least a 30% improvement
• Relative risk = 1.52 (CI 1.22, 1.99, p = 0.0002)
• Number needed to treat of 7.5

Between group difference: Pain Interference

<table>
<thead>
<tr>
<th>Measure</th>
<th>Stepped-care Mean (SD)</th>
<th>Usual care Mean (SD)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline BPI</td>
<td>5.4 (2.1)</td>
<td>5.4 (2.4)</td>
<td>0.86</td>
</tr>
<tr>
<td>9-month BPI</td>
<td>3.8 (2.6)</td>
<td>4.5 (2.7)</td>
<td>0.031</td>
</tr>
<tr>
<td>Change</td>
<td>-1.7 (-2.1, -1.3)</td>
<td>-0.9 (-1.2, -0.05)</td>
<td>0.0033</td>
</tr>
</tbody>
</table>

Between group difference of -0.8 points (-1.3 to -0.3)

Between group difference: Pain Severity

Limitations

• All Veterans; results apply to other patients?
• Conducted at a single medical center.
• Tested a multi-modal intervention and used a “bundled” approach to delivery. – relative effect of intervention components?

Study Strengths

• High-priority study population
• Approach that challenges existing treatment paradigms for chronic pain
• Telephone-based intervention – Delivered by nurse care managers – May be applied across multiple geographically dispersed clinical settings

Study Summary

• A stepped-care intervention – Combination of analgesics, self-management strategies, and CBT
• Reduced: – Pain-related disability – Pain interference with activities – Pain severity
• Veterans with chronic, disabling musculoskeletal spine and extremity pain
SCAMP Study

Stepped Care for Affective disorders and Musculoskeletal Pain

Funding Sources: NIMH Grant No: R01 MH071268 (Kroenke) and VA HSR&D Career Development Award (Bair)

Why Pain and Depression?

- **Common**: most common symptoms in primary care
- **Comorbid**: co-occur 30% to 50% of time
- **Combined effects**: adverse health outcomes

Why Pain and Depression?

- **Disabling**: two of the top causes of lost work
- **Costly**: 50-100 billion dollars/yr in US for each
- **Challenging**: PCPs need better strategies to manage

Study Objective

- To determine if a stepped-care intervention improves:
  - Both pain and depression
  - In primary care patients with comorbid musculoskeletal pain and depression

Pain-Depression Dyad

Pain

Depression

SCAMP Trial Design

- **PAIN and DEPRESSION**
- **Stepped Care**
  - Step 1: Optimized antidepressant therapy
  - Step 2: Pain self-management program
- **Usual Care**

Assessments at baseline, 1, 3, 6, and 12 months
**SCAMP Eligibility Criteria**

- **Primary care** patients in university or VA clinic
- **Pain** that is
  - Musculoskeletal (low back, hip, or knee)
  - Moderately severe (BPI ≥ 5)
  - Persistent ≥ 3 months despite 2 analgesics
- **Depression** that is
  - Moderately severe (PHQ-9 ≥ 10)

**Intervention Group**

- Optimized antidepressant therapy
  - Medication algorithm
  - Delivered by nurse care managers
  - Supervised by study physicians

**Antidepressant Algorithm**

<table>
<thead>
<tr>
<th>Order</th>
<th>Antidepressant</th>
<th>Class</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Venlafaxine</td>
<td>SNRI*</td>
<td>75mg to 225mg/day</td>
</tr>
<tr>
<td>2</td>
<td>Fluoxetine</td>
<td>SSRI</td>
<td>20mg to 40mg/day</td>
</tr>
<tr>
<td>3</td>
<td>Sertraline</td>
<td>SSRI</td>
<td>50mg to 200mg/day</td>
</tr>
<tr>
<td>4</td>
<td>Citalopram</td>
<td>SSRI</td>
<td>20mg to 40mg/day</td>
</tr>
<tr>
<td>5</td>
<td>Buproprion</td>
<td>Other</td>
<td>100mg to 300mg/day</td>
</tr>
<tr>
<td>6</td>
<td>Mirtazepine</td>
<td>Other</td>
<td>15mg to 45mg/day</td>
</tr>
</tbody>
</table>

*SNRI = Serotonin Norepinephrine Reuptake Inhibitor; SSRI = Selective Serotonin Reuptake Inhibitor

**Pain Self-Management Program**

(6 sessions over 12 weeks)

- Education – pain; vocabulary; red flags;
- Identifying /modifying fears and beliefs
- Goal-setting and problem-solving
- Exercise – strengthening; aerobic; etc.
- Relaxation; deep-breathing;
- Handling pain flare-ups
- Working with clinicians and employers

**Care Manager Contacts**

<table>
<thead>
<tr>
<th>When</th>
<th>Where</th>
<th>What (Treatment Action)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Clinic</td>
<td>Start antidepressant</td>
</tr>
<tr>
<td>1 wk</td>
<td>Phone</td>
<td>Check adherence &amp; side effects</td>
</tr>
<tr>
<td>3 wk</td>
<td>Phone</td>
<td>Assess depression response</td>
</tr>
<tr>
<td>6 wk</td>
<td>Clinic</td>
<td>Change antidepressant</td>
</tr>
<tr>
<td>9 wk</td>
<td>Phone</td>
<td>Adjust dose</td>
</tr>
<tr>
<td>12 wk</td>
<td>Clinic</td>
<td>Assess depression response</td>
</tr>
</tbody>
</table>

**DETAILS OF TREATMENT**

- All aspects of intervention delivered by nurse case manager
- Weekly case management meetings
- Regular contacts with participants to
  - Monitor pain/disability
  - Response to treatment
  - Introduce self-management strategies
Control Group

- Treatment-as-usual
- Informed of depressive symptoms
- Recommended to seek treatment advice
- No other attempts to provide treatment
  - Unless psychiatric emergency (e.g. suicidal ideation)

Baseline Characteristics

- Mean age = 56 yrs
- Women, 53%
- 60% white, 36% black
- Employment status
  - 20% employed
  - 31% not working
  - 43% retired
- University clinic 59%
- VA clinic 41%
- Back pain: 60%
- Hip/leg pain: 40%
- Baseline treatments
  - 45% on opioid
  - 36% antidepressant

Baseline Depression and Pain

<table>
<thead>
<tr>
<th>Depression and Pain Measures</th>
<th>Intervention (n = 123)</th>
<th>Usual Care (n = 127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCL-20 depression* (0-4)</td>
<td>1.83</td>
<td>1.84</td>
</tr>
<tr>
<td>Major depression + dysthymia</td>
<td>73% + 23%</td>
<td>76% + 19%</td>
</tr>
<tr>
<td>Pain severity* (0-100)</td>
<td>72.7</td>
<td>72.8</td>
</tr>
<tr>
<td>Pain disability (0-100)</td>
<td>67.8</td>
<td>70.2</td>
</tr>
<tr>
<td>Disability days (past 3 months)</td>
<td>34.9 days</td>
<td>38.0 days</td>
</tr>
</tbody>
</table>

* Higher scores = worse depression and pain severity

SCAMP Depression Outcomes

- RR = 2.3 (1.5-3.2)
- RR = 2.4 (1.6-3.2)
- RR = 3.3 (1.8-5.4)

SCAMP Pain Outcomes

- DEPRESSION (≥ 50% decrease)
- PAIN (≥ 30% decrease)
- BOTH
SCAMP Study Findings

- Substantial improvements in depression severity, response, and remission rates
- Moderate benefits in pain severity and disability

Summary

- 1st trial of primary care patients w/ comorbid pain and depression
- Stepped-care produced:
  - Large improvements in depression
  - Moderate improvements in pain
- Additional strategies to co-manage pain may be needed to improve pain outcomes

Clinical and Policy Implications

- Aligned well with VA Pain Directive
  - Stepped care approach to delivering pain services
- Nurse Care Management already used extensively in VA and other health care systems

Summary

- A stepped-care approach to manage chronic back pain (CBP) is effective
- We discussed specific tasks a pain care manager may play in treating CBP
- Reviewed an algorithm for analgesic management of CBP