

**CUD Update in Pain Medicine
2007 SGIM Annual Meeting
Friday, Apr 27 2007 10:30AM - 12:00PM
Sheraton Centre Toronto Dominion Ballroom North, Second Floor**

WORKSHOP FACULTY:

Session Coordinator(s):

Matthew J. Bair, MD, MS
Assistant Professor of Medicine
Roudebush VA Center of Excellence for Implementation of Evidence Based Practice
Indianapolis, IN
1481 W. 10th Street (11-H)
Indianapolis, IN 46202
mbair@iupui.edu
Phone: (317) 988-2058

Daniel P. Alford, MD, MPH, FACP
Associate Professor of Medicine
Boston University School of Medicine
Boston, MA
Section of General Internal Medicine
91 East Concord Street, Suite 200
Boston, MA 02118
dan.alford@bmc.org
Phone: (617) 414-7399

Additional Faculty:

Karina M. Berg, MD, MS
Assistant Professor of Medicine
Albert Einstein College of Medicine

Jennifer Gibson, MD,
Assistant Professor of Medicine
Legacy Good Samaritan Hospital,

Christina Nicolaidis, MD, MPH
Assistant Professor of Medicine and Public Health
Oregon Health And Science University

Michael Picchioni, MD
Assistant Professor of Medicine
Baystate Medical Center/Tufts University School of Medicine

Ian A Chen, MD, MPH
Assistant Professor of Medicine
Eastern Virginia Medical School

Jane Liebschutz, MD, MPH, FACP
Assistant Professor of Medicine
Boston University School of Medicine

Mukta Panda, MD
Assistant Professor of Medicine
University of Tennessee-Chattanooga

Update in Pain Medicine

Handout Content

Section 1: **Opioids and Chronic Pain**

Section 2: **Chronic Pain and Comorbidity (Depression and Substance Use Disorders)**

Section 3: **Management Approaches/Issues in Primary Care**

Section 4: **Pharmacologic Modalities for Pain**

Section 5: **Interventional Modalities for Pain**

Section 6: **Complementary and Alternative Modalities for Pain**

Section 1: Opioids and Chronic Pain

Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy and Association with Addiction. Martell BA et al. Annals of Internal Medicine 2007; 146:116-127

Background:

- Back pain is second leading symptom seen by US physicians
- The prevalence, efficacy and risk for addiction for persons receiving opioids for chronic low back pain are unclear

Aims/purpose:

- To determine the prevalence of opioid treatment, whether opioid medications are effective and the prevalence of substance abuse disorders among patients receiving opioid medications for chronic back pain.

Methods:

- Systematic review and meta-analysis of English-language studies of adult, non-obstetric sample using oral, topical or transdermal opioids for treatment of chronic back pain.

Results:

- Opioid prescribing rates in 11 studies varied widely by treatment setting (3% to 66%) with prevalence estimates highest in specialty treatment and lowest in primary care centers.
- Of the 4 studies assessing efficacy of opioids compared to placebo or a nonopioid, opioids have limited efficacy.
- The 5 studies comparing efficacy of different opioids, demonstrated a nonsignificant reduction in pain from baseline.
- Of the 5 studies that reported prevalence of aberrant medication-taking behaviors, the current prevalence estimates ranged from 5-24%

Author conclusion:

- Opioids are commonly prescribed for chronic back pain and may be efficacious for short-term pain relief.
- Long-term efficacy (\geq 16 weeks) is unclear.
- Limited information indicates that up to one quarter of patients receiving opioids for chronic back pain exhibit aberrant medication-taking behaviors that may be interpreted as signs of abuse.
- There are substantial concerns about the quality of the literature addressing this common clinical problem, thus future research is needed to guide clinicians.

Importance for Internists:

- Opioids seem to have limited, short-term (<4 months) value in chronic low back pain.
- Long-term trials of opioid efficacy are lacking
- Evidence about developing substance abuse is too limited to draw any conclusions.

Background:

- Chronic non-cancer pain (CNCP) is a major health problem.
- Evidence is lacking about side effects, efficacy, and risk of misuse.

Aims/purpose:

- To determine the efficacy of opioids for CNCP compared with placebo.
- To compare the effectiveness of opioids for CNCP with that of other drugs.
- To identify categories of CNCP with better response to opioids.
- To determine the most common side effects and complications of opioid therapy for CNCP, including opioid addiction and sexual dysfunction.

Methods:

- The authors searched MEDLINE, EMBASE, and other electronic databases for randomized controlled trials of any opioid administered by any route for CNCP (longer than 6 months).
- Extracted outcomes included pain, function, and side effects.
- Drop out rates averaged 33% in opioid groups and 38% in placebo groups.

Results:

- 41 randomized controlled trials were included involving 6019 patients. Methodological quality was high in 87% of studies. 80% of patients had nociceptive pain, 12% had neuropathic pain, and 7% had fibromyalgia. Average treatment duration was five weeks (range 1-16 weeks).
- Opioids were more effective than placebo for both pain and functional outcomes in patients with nociceptive pain, neuropathic pain, or fibromyalgia.
- Strong opioids (morphine, oxycodone) but not weak (tramadol, propoxyphene, codeine) were significantly superior to naproxen and nortriptyline for pain relief but not for function or side effects.
- Constipation and nausea were the only significant side effects of opioids.
- Data were insufficient to assess the side effects of opioid addiction, sexual dysfunction and hypogonadism, route of administration, long-term efficacy, or tolerance.

Author conclusions:

- All opioids (weak and strong) were more effective than placebo for pain and functional outcomes.
- Only strong opioids were superior to other drugs (NSAIDs or tri-cyclic antidepressants) and this was true for pain outcomes but not for functional outcomes.
- Overall, trials were of short duration and had high dropout rates.

Importance for Internists:

- Using pooled data, compared to placebo, opioids decrease pain and increase function in patients with CNCP.
- Weak opioids are not more effective than NSAIDs or tri-cyclic antidepressants for decreasing pain or increasing function.
- Existing data are insufficient to assess the risk of opioid addiction.

Background:

- Primary care attitudes affecting the use of strong opioids in pain management have changed considerably.
- Forces that have shaped current attitudes and trends in opioid prescribing include historical influences, regulatory factors, and technologic and scientific advances.

Aims/purpose:

- This paper reviews the literature on challenges and advances in noncancer pain management
- Divided into three topic areas.

Content:

- The first section is “Factors influencing treatment success or failure”. In this section, the author acknowledges patient fears about opioids and discusses the literature on safety and addiction risk so that physicians can provide reassurance to their patients who may benefit from opioids.
- Risk management programs are then reviewed. These programs are designed to identify potential prescription drug abusers and provide guidelines for the management of patients to avoid or identify situations in which drug diversion may occur.
- Risk management programs are multidimensional and include addiction risk assessment tools such as the Screener and Opioid Assessment for Patients with Pain (SOAPP). This section ends with the advantages and disadvantages of various tools for assessing pain.
- The second section focuses on practical aspects of using opioids in clinical practice, including suggestions for initialing and titrating opioid pain medications, and monitoring patients for adverse events. Important areas are discussed including multimodal analgesia, issues of polypharmacy, variable patient responses to the effects of opioids, and opioid rotation.
- The final section, which covers advances in opioid treatments for pain, gives an update on ongoing research in new routes of administration and new formulations.

Importance for Internists:

- The article identifies for primary care physicians the current challenges and issues surrounding the use of opioid analgesics for noncancer pain
- Examines how new technology and expanding knowledge have been applied to existing opioids to address continuing challenges in pain management.

Background:

- During last two decades a significant increase in use of opioids for chronic non-cancer pain has occurred without scientifically relevant long-term studies

Aims/purpose:

- To evaluate the long-term effects of opioids on pain relief, quality of life and functional capacity in long-term/chronic non-cancer pain.

Methods:

- Cross sectional epidemiologic study of individuals with long lasting (>6 months) chronic noncancer pain based on data from the 2000 Danish Health and Morbidity Survey (Random sample of 16,684 persons >16 years of age to complete self-administered questionnaire and face-to-face interview to evaluate and monitor general health status and morbidity)
- Persons reporting pain were divided into opioid and non-opioid users
- Pain relief, quality of life (SF-36) and functional capacity among opioid users were compared to non-opioid users.
- Data on Danish opioid consumption during 1981-2002 obtained from Danish Pharmaceutical Information

Results:

- Of the 16,684 persons sampled, 10,066 completed both questionnaire and interview, of which 1,906 (19%) had chronic pain, of which 228 (12%) were opioid users and 1,678 (88%) were non-opioid users.
- Opioid usage was significantly associated with reporting moderate/severe/ very severe pain, poor self-related health, unemployment, higher use of health care system and negative influence on quality of life by SF-36
- There was an over seven-fold increase in opioid consumption in Denmark between 1984-2002.

Author conclusions:

- Although no causative relationships can be ascertained, opioid treatment of long-term/chronic non-cancer pain does not seem to fulfill any of the key outcome opioid treatment goals: pain relief, improved quality of life and improved functional capacity

Importance for Internists:

- There no longitudinal randomized controlled trials to help determine whether the long-term effects and consequences of opioids for pain, are beneficial or harmful.
- Based on the findings of this study, caution should be used with long-term opioid treatment of pain, at least until there is better evidence on efficacy and outcomes.

Objective:

- To determine the prevalence of opioid prescribing by PCPs and any changes in prescribing over a 10 year time period and to identify factors associated with opioid prescribing.

Design/Setting/Participants:

- Cross-sectional analyses from the 1992-2001 National Ambulatory Medical Care Survey
- Nationally representative annual panel study of approximately 2000 physicians and 28,000 patient visits in a variety of practice and geographical settings.
- 48,000 visits to primary care were analyzed.

Results:

- In 1992, 41 opioids were prescribed per 1000 primary care visits, rising to 63 per 1000 primary care visits in 1998-99 and 59 in 2000-01.
- Patients were more likely to be prescribed opioids if they were receiving Medicaid (Odds Ratio 2.09), or Medicare (2.00) and also being prescribed a NSAID (2.77).
- Patients were less likely to be opioids if they were Hispanic (OR 0.67), Asian/Native American (OR 0.68), from the northeast (OR 0.60) or midwest (OR 0.75).
- When compared to opioid prescriptions in whites, there was no difference in African-Americans (OR 0.93)

Author conclusions:

- Opioid prescribing by primary care physicians increased from the early 1990s to the early 2000s, with substantial variation in prescribing due to geography, ethnicity and insurance status.

Comment:

- This study reflects the impact of non-medical influences on opioid prescribing practices. The data also suggests that people who are disabled and sicker are more likely to be prescribed opioids.

Importance for Internists:

- Get to know and adhere to standard practices when prescribing opioids.

Trends and Geographic Variation of Opiate Medication Use in State Medicaid Fee-for-Service Programs, 1996 to 2002. Zerzan JT et al. Medical Care 2006; 44(11):1005-10.

Background:

- Although geographic variation in hospital and surgical care has been described, little research has examined variation in prescription drug use
- Variation in prescription drug use may influence outcomes and quality of care

Aims/purpose:

- Measure the variability across state Medicaid programs in opiate use
- Compare the changes in opiate prescriptions to the changes in prescription medications in general during the period 1996 to 2002

Methods:

- Review of adult, outpatient Medicaid fee-for-service dispensing records from 49 states during the period 1996 to 2002
- Defined daily dose of per 1000 Medicaid enrollees per day calculated for all opiate medications
- Market basket of non-pain prescription medications
- Rates, trends and coefficient of variation determined by year and for each state

Results:

- Overall use of pain medications increased during this period (average total dispensing increased 309%) and did so at almost twice the rate of non-pain related prescription medications (increased 170%)
- Total opiate prescribing varied widely from state to state with a 23-fold difference between highest and lowest use states
- Greatest increase in opiate prescribing was in oxycodone (1615% increase) and methadone (790% increase)
- Increasing coefficient of variation in opiate prescribing during this time

Author Conclusions:

- Increasing coefficient of variation shows that variability in dispensing of these medications is growing over time
- Variability may be related to state policies regarding utilization management, differences in drug marketing
- Striking increase in opiate prescribing may be related to regulatory changes, marketing changes, attitude changes

Objective:

- To determine whether race plays a role in treatment decisions involving primary care patients with chronic non-malignant pain (CNMP).

Design/Setting/Participants:

- Cross-sectional survey of patients with CNMP and their physicians at 12 academic medical centers.

Results:

- 397 black and white patients were included in this analysis.
- Blacks had higher pain scores (6.7 vs. 5.6), but were less likely to be taking opioids (32% vs 46%, $p < 0.006$).
- Whites were more likely to be taking opioids even after adjustment for potential confounders (OR 2.67, 95%CI 1.71-4.15).
- Racial differences were more pronounced when considering stronger opioids (OR 3.62; 95%CI 1.75-7.46) and longer-acting opioids (OR 3.08; 95%CI 1.35-7.06).
- There was no difference by race in other measured therapies, including NSAIDs, physical therapy, or referral services.

Summary:

- Despite equal treatment by race in nonopioid-related therapies and higher pain scores, black patients were less likely than whites to be treated with opioids.

Comment:

- The authors argue that since nonopioid-related therapies were similar between whites and blacks, access to care is unlikely to explain the difference in opioid use.
- Similarly, they argue that since black patients had higher pain scores, racial disparities are not likely due to patient preference or behaviors.
- They did not, however, specifically ask patients about preferences, coping styles, or attitudes toward opiates, which may in fact be culturally driven.
- Regardless, their finding of a significant racial disparity in the treatment of CNMP has very important implications regarding potential provider under-treatment of CNMP in minorities and the need for cultural competence and pain management training amongst primary care providers.

Background:

- Opioid contracts in chronic nonmalignant pain management have been increasingly employed by physicians in primary care.
- Belief that opioid contracts improve the quality of care and address concerns about opioid abuse
- Pain management experts and professional societies recommend the use of contracts.
- Despite widespread acceptance, there are no systematic guidelines

Aims/purpose:

- Review the principal objectives and ideal elements of opioid contracts
- Examine the limited empirical evidence for the effectiveness of contracts
- Identify areas of uncertainty and of ethical concern regarding their implementation
- Offer some tentative suggestions for how to draft and use contracts.

Methods:

- Four justifications for opiate contracts are critically examined: adherence, informed consent, legal risk and efficacy.
- Contract objectives, evidence for their use and ethical issues are discussed.

Results:

- Adherence: no rigorous empirical studies evaluating the efficacy of opioid contracts in improving adherence.
- Informed consent: opioid contracts do not promote informed consent but rather promote shared decision-making
- Legal risk: diminution of legal risk is plausible but remains unproven
- Practice efficiency: promotion of improved efficiency is possible but has no empirical evidence of support.
- Ethical issues relate to how contracts are implemented.

Author conclusions:

- Clinicians should exercise caution in implementing opioid contracts due to the lack of consensus and empirical evidence, as well as potential ethical problems.
- More research is needed to sort out opiate contract uncertainties.

Importance for Internists:

- Primary care clinicians contemplating use of opioid contracts in treating patients with chronic nonmalignant pain need to be sensitive to the lack of empirical evidence regarding their effectiveness and to the ethical concerns over their implementation.

Background:

- The use of opioid medications to manage chronic pain is complex and challenging, especially in primary care settings.
- Medication contracts are increasingly being used to monitor patient adherence, but little is known about the long-term outcomes of such contracts.

Aims/purpose:

- To describe the long-term outcomes of a medication contract agreement for patients receiving opioid medications in a primary care setting.

Methods:

- Retrospective cohort study.
- All patients placed on a contract for opioid medication between 1998 and 2003 in an academic General Internal Medicine teaching clinic.
- Demographics, diagnoses, opiates prescribed, urine drug screens, and reasons for contract cancellation were recorded. The association of physician contract cancellation with patient factors and medication types were examined using the Chi-square test and multivariate logistic regression.

Results:

- A total of 330 patients constituting 4% of the clinic population were placed on contracts during the study period. Seventy percent were on indigent care programs. The majority had low back pain (38%) or fibromyalgia (23%).
- Contracts were discontinued in 37%. Only 17% were cancelled for substance abuse and noncompliance. Twenty percent discontinued contract voluntarily.
- Urine toxicology screens were obtained in 42% of patients of whom 38% were positive for illicit substances.

Author Conclusions:

- Over 60% of patients adhered to the contract agreement for opioids with a median follow-up of 22.5 months.
- Our experience provides insight into establishing a systematic approach to opioid administration and monitoring in primary care practices.
- A more structured drug testing strategy is needed to identify nonadherent patients.

Importance for Internists:

- Concerns about the safety of long-term use of opioids necessitate “systems approaches” such as this one for close therapeutic monitoring.

Section 2: Chronic Pain and Comorbidity (Depression, Substance Use Disorders)

Comorbid Depression, Chronic Pain, and Disability in Primary Care. Arnow BA et al. Psychosomatic Medicine 2006;68:262-68.

Background:

- Both chronic pain and major depressive disorder (MDD) are generally treated in the primary care setting, though the strength of association between the two conditions is unclear.

Aims/purpose:

- To estimate the prevalence and strength of association between major depression and chronic pain in a primary care population
- To examine the clinical burden associated with chronic pain and depression, singly and together.

Methods:

- Patients from 31 outpatient clinics of the Kaiser Permanente HMO in northern California were randomly selected within one week of their primary care visit to receive a mailed survey.
- Outcome measure: All eligible and consented patients completed a questionnaire assessing major depressive disorder (MDD), chronic pain, pain-related disability, somatic symptom severity, panic disorder, other anxiety, probable alcohol abuse, and health-related quality of life (HRQL).
- 5808 patients were studied.

Results:

- Among those with MDD, a significantly higher proportion reported chronic (i.e., nondisabling or disabling) pain than those without MDD (66% versus 43%, respectively). Disabling chronic pain was present in 41% of those with MDD versus 10% of those without MDD.
- Respondents with comorbid depression and disabling chronic pain had significantly poorer HRQL, greater somatic symptom severity, and higher prevalence of panic disorder than other respondents.
- The prevalence of probable alcohol abuse/dependence was significantly higher among persons with MDD compared with individuals without MDD regardless of pain or disability level.
- Compared with participants without MDD, the prevalence of other anxiety among those with MDD was more than sixfold greater regardless of pain or disability level.

Author conclusions:

- Chronic pain is common among those with MDD.
- Comorbid MDD and disabling chronic pain are associated with greater clinical burden than MDD alone.

Importance for internists:

- Attention to assessment and treatment of chronic pain and depression concurrently seems necessary for the best outcomes

Background:

- Non-medical use of prescription opioids is a growing public health concern but risk factors for opioid misuse have not been well characterized

Aims/purpose:

- To determine the incidence and predictors of opioid misuse in a cohort of patients enrolled in a chronic pain disease management program within an academic general internal medicine practice.

Methods:

- This is a one-year prospective cohort study of patients newly enrolled in a chronic pain disease management program.
- Participants were eligible for the chronic pain disease management program if they had non-cancer pain of greater than three months duration. Referral to the program was encouraged for patients whose pain was difficult to manage or who were suspected of opioid misuse.
- The outcome variable of opioid misuse was a composite variable defined as **any one** of the following: (1) “negative urine toxicology” = urine toxicology test results that are negative for the prescribed medications in the context of the patient saying they have been taking the medication as prescribed; (2) “inconsistent urine toxicology” = urine toxicology test results that are positive on at least two occasions for non-prescribed opioids; (3) “doctor collecting” = evidence of concurrent procurement of opioids from multiple providers; (4) diversion; (5) prescription forgery; (6) “stimulant positive urine toxicology” = urine toxicology test results that are positive for cocaine or amphetamines.
- Independent variables included socio-demographic characteristics, pain severity, pain-related disability, depression, literacy, self-reported cocaine or alcohol use, and past drug or alcohol-related criminal convictions.

Results:

- 196 of 199 referred participants agreed to participate. 55% were male and 75% were white with a mean age of 52 years.
- Over the one-year study period, opioid misuse occurred in 63 participants (32%).
- The most common category of opioid misuse was “stimulant positive urine toxicology”, followed in order of decreasing prevalence by “negative urine toxicology”, “doctor collecting”, “inconsistent urine toxicology”, prescription forgery, and diversion.
- Predictors of opioid misuse included age [OR=0.95; 95%CI (0.90-0.99)], drug or alcohol-related criminal convictions [OR=2.58; 95%CI (1.01-6.59)], history of cocaine abuse [OR=4.30; 95%CI (1.76-10.4)], and history of alcohol abuse [OR=2.60; 95%CI (1.12-6.26)].

Author conclusions:

- Opioid misuse occurred frequently in a referral population of chronic pain patients in a chronic pain disease management program with in an academic primary care practice.
- Patients with prior alcohol or cocaine abuse as well as patients with prior drug or alcohol-related convictions should be carefully monitored for signs of misuse after opioids are prescribed.

Importance for Internists:

- Despite that this is a referred population; results suggest that internists who prescribe opioids for chronic pain should be vigilant about monitoring patients with past alcohol or cocaine abuse for signs of prescription opioid misuse.

Background:

- Specialists in pain medicine cannot possibly assume care for all patients with chronic pain, numbering in the tens of millions.
- Primary care providers shoulder most of the burden of pain management despite having received little specific training in pain medicine or addictionology and being generally constrained to brief visits for evaluating and managing complex problems.

Aims/purpose:

- To measure the impact of a structured opioid renewal program for chronic pain run by a nurse practitioner (NP) and clinical pharmacist in a primary care setting.

Methods:

- Naturalistic prospective outcome study.
- Patients and Setting: patients with chronic noncancer pain managed with opioid therapy in a primary care clinic staffed by 19 providers serving 50,000 patients at an urban academic Veterans hospital.
- Intervention: based on published opioid prescribing guidelines and focus groups with primary care providers (PCPs), a structured program, the Opioid Renewal Clinic (ORC), was designed to support PCPs managing patients with chronic noncancer pain requiring opioids. After training in the use of opioid treatment agreements (OTAs) and random urine drug testing (UDT), PCPs worked with a pharmacist-run prescription management clinic supported by an onsite pain NP who was backed by a multi-specialty Pain Team.
- After 2 years, the program was evaluated for its impact on PCP practice and satisfaction, patient adherence, and pharmacy cost.

Results:

- A total of 335 patients were referred to the ORC.
- Of the 171 (51%) with documented aberrant behaviors, 77 (45%) adhered to the OTA and resolved their aberrant behaviors, 65 (38%) self-discharged, 22 (13%) were referred for addiction treatment, and seven (4%) with consistently negative UDT were weaned from opioids.
- The 164 (49%) who were referred for complexity including history of substance abuse or need for opioid rotation or titration, with no documented aberrant drug-related behaviors, continued to adhere to the OTA.
- Use of UDT and OTAs by PCPs increased.
- Significant pharmacy cost savings were demonstrated.

Author Conclusions:

- An NP/clinical pharmacist-run clinic, supported by a multi-specialty team, can successfully support a primary care practice in managing opioids in complex chronic pain patients.

Importance for Internists:

- This innovative program demonstrated an effective integration of pain medicine and primary care for managing opioids in patients with chronic pain and a history of substance use disorders

Background:

- Chronic widespread pain (CWP), the cardinal symptom of fibromyalgia, is prevalent and co-occurs with numerous symptom-based conditions such as chronic fatigue syndrome, joint pain, headache, irritable bowel syndrome, and psychiatric disorders.
- Few studies have examined the comorbidities of CWP in the general population.
- Little is known about the importance of familial (genetic and family environmental) factors in the etiology of co-occurrence.

Aims/purpose:

- To assess a wide range of comorbidities of CWP in a large community sample of nearly 45 000 individuals.
- To evaluate the influences of unmeasured genetic and family environmental factors that confound the associations of comorbidities with CWP

Methods:

- 2-stage approach that included a classic case-control design and co-twin control design.
- Data were obtained from 44,897 individuals in the Swedish Twin Registry via computer-assisted telephone interview from 1998 through 2002 (age ≥ 42 years; 73.2% response rate).
- Screening for CWP was based on the American College of Rheumatology criteria without clinical evaluation.
- Measures for comorbidities were based on standard criteria when available.
- Odds ratios (ORs) were calculated in case-control and co-twin control designs to assess the effect of familial confounding in the associations.

Results:

- Considerable co-occurrences were found in CWP cases for chronic fatigue (OR, 23.53; 95% confidence interval [CI], 19.67-28.16), joint pain (OR, 7.41; 95% CI, 6.708.21), depressive symptoms (OR, 5.26; 95% CI, 4.755.82), and irritable bowel syndrome (OR, 5.17; 95% CI, 4.55-5.88).
- In co-twin control analyses, ORs were no longer significant for psychiatric disorders, whereas they decreased but remained significant for most other comorbidities. No changes in ORs were observed for headache.

Author conclusions:

- Associations between CWP and most comorbidities are mediated by unmeasured genetic and family environmental factors in the general population.
- The extent of mediation via familial factors is likely to be disorder specific.

Importance for internists:

- There is significant overlap in underlying mechanisms of CWP and its comorbidities (chronic fatigue, chronic headaches, and psychiatric comorbidity)

Section 3: Management Approaches/Issues in Primary Care

Self Management of Arthritis in Primary Care: Randomized Controlled Trial. Buszewicz M et al. BMJ 2006 Oct 28;333(7574):879

Background:

- Literature suggests self management programs (SMP) for patients with chronic diseases may produce improved outcomes – more information is needed regarding the efficacy of such a program for osteoarthritis.

Aims/purpose:

- Evaluation of the efficacy of a SMP for osteoarthritis of hip/knee

Methods:

- RCT in general practices in the United Kingdom.
- 812 patients randomized to SMP+education booklet versus education booklet alone.
- Primary outcome was quality of life (SF-36), evaluation of other physical/psychosocial secondary outcomes at 0, 4mo, and 12months.

Results:

- At 12 months, no differences were seen between the SMP versus normal group in terms of SF36 subscales (mental +1.35[-0.03 to 2.74], physical +0.33[-1.31 to 1.98], or WOMAC osteoarthritis index.
- Slight decreases were seen in anxiety, and slight increases were seen in patient self efficacy (pain +0.98[0.07 to 1.89], other 1.58[0.25 to 2.90].
- No differences were seen in number of office visits

Author Conclusions:

- No significant differences were seen in pain, physical functioning, or contact with primary care
- The intervention did have an impact on psychological wellbeing – by reducing anxiety and increasing self-efficacy.
- The clinical relevance of improved psychological wellbeing and how to best target and deliver this intervention remains unclear.

Importance for Internists:

- SMP for arthritis do not currently justify a policy of active recruitment in primary care.

**Primary Care Provider Concerns about Management of Chronic Pain in Community Clinic Populations.
Upshur CC et al. Journal of General Internal Medicine 2006;21:652-655.**

Background:

- Previous studies have documented multiple challenges such as poor provider training caring for & low satisfaction treating chronic pain patients.

Aims/purpose:

- Evaluation of providers' views in community clinic settings regarding chronic pain management

Methods:

- Cross-sectional survey in 8 ethnically diverse community health centers in Massachusetts

Results:

- 111 surveys returned.
- The most common issues identified by providers included lack of patient self-management and compliance, and patient psychological factors.
- Adequacy of training regarding pain management was universally reported low for NP/PA programs, medical school education and postgraduate medical education.

Author Conclusions:

- 1/3 of all appointments involved a patient with chronic pain
- Providers feel poorly prepared and dissatisfied with chronic pain patients.
- However, providers identify patient compliance and behavioral problems as more problematic than self education in treating chronic pain

Importance for Internists:

- Patient centered care approaches addressing compliance and behavioral problems may be helpful.

Background:

- The use of chronic opioids for noncancer pain is a common and difficult problem in primary care

Aims/purpose:

- To test the attitudes and behavior of internal medicine residents and attendings who participated in a shared decision-making model for opioid treatment

Methods:

- RCT of 45 IM residents (38) and attendings (7) in Seattle, WA randomized to two 1-hour training sessions versus written educational materials.
- Self-reported outcomes regarding satisfaction, patient centeredness, prescribing practices, and rates of treatment agreements measured at 2 months before and 3 months after training

Results:

- Improved satisfaction, relationship quality, appropriate use of time, and information giving were seen in the intervention group.
- Intervention physicians were also more likely to prescribe methadone (30% vs 10%), set functional goals, and use patient treatment agreements (95% vs 67%)

Author Conclusions:

- Two hours of training for physicians in a shared decision making model improved physician attitudes and behaviors towards opioid treatment of chronic pain.
- Satisfaction and clinical outcomes are unknown.

Importance for Internists:

- Physician sense of collaboration and satisfaction in treatment chronic pain patients can be improved in a shared decision-making model

A Controlled Trial of Methods for Managing Pain in Primary Care Patients with or without Co-occurring Psychosocial Problems. Ahles T et al. Annals of Family Medicine 2006;341-350.

Background:

- Treatment of pain may be improved with better self-management programs (SMP), backed up by telephone-based assistance to teach problem-solving strategies and pain management skills.

Aims/Purpose:

- Test efficacy of SMP (INFOFEED) with nurse-educator (NE) assistance in chronic pain patients with and without psychosocial problems.

Methods:

- RCT of 1066 patients in VT,NH,ME assigned to usual care or SMP (patient information + MD feedback) or SMP+NE telephone contact.
- SF-36 score, Functional Interference Estimate (FIE) & healthcare utilization at 0,6,12 mos.

Results:

- SMP improved social functioning subscale of SF36 and FIE score at 6 months, but not at 12 months.
- SMP+NE showed improvements over usual care at 12 months for vitality, role emotional, and FIE with a trend for bodily pain.
- No differences were seen in utilization (total doctor visits, days in hospital, days in bed)

Author Conclusions:

- In patients with pain and psychosocial problems, telephone-based intervention with cognitive-behavioral pain management strategies and problem solving therapy along with SMP (pt info+MD feedback) can reduce pain and improve psychosocial and physical function to a meaningful degree as measured by SF36.

Importance for Internists:

- Nurse educator support with patient information/physician feedback may be an important treatment program for chronic pain patients with psychosocial problems.

Primary Care Clinicians Treat Patients with Medically Unexplained Symptoms: A Randomized Controlled Trial. Smith RC, et al. Journal of General Internal Medicine 2006;21:671-677.

Objective:

- To conduct a trial of cognitive behavior therapy, pharmacological intervention and other treatment modalities for medically unexplained symptoms.

Design/Setting/Participants:

- A randomized controlled trial in a Midwestern HMO of a 12 month treatment protocol delivered by a nurse practitioner compared to care as usual.
- The treatment included a series of 12 planned visits throughout the year during which a behaviorally defined 5-step patient-centered method for relationship building and communication enhancement as well as a 3-step motivation and educational intervention were employed.
- In addition, anti-depressants, reduction of controlled substances, and other stress-reduction and physical activity modalities were used.
- Eligible patients were high utilizers of health care, who had symptoms that were not explained by primary organic disease.
- The main outcome was a 4 point improvement on the mental component summary score of the SF-36, a health related quality of life measure.

Results:

- Of the 200 patients who completed the study (97%), more patients in the treatment group compared to the controls improved (48% vs. 34%, OR 1.9).
- The NNT for improvement was 6.4.
- Other improvements in the treatment group included decreased depressive symptoms, and improved disability scores.
- More treatment subjects received full dose anti-depressants (68% vs. 20%) and more decreased use of controlled substances (70% vs. 14%).
- Use of antidepressants in full doses was strongly associated with improved outcomes.

Author Conclusions:

- Use of a multidimensional intervention led to clinical improvement in patients with Medically Unexplained Symptoms.

Comments:

- This is a resource intense intervention by nurse practitioners that has relatively good effect for approximately half of this group of hard-to-treat patients.
- The key factor appeared to be taking full dose anti-depressants, which was greatly augmented by the intervention.
- Future studies should evaluate whether a focus on patient adherence to the anti-depressant medication in full doses would be equivalent to the entire behavioral intervention.
- It is unclear whether this intervention would be effective for patients with pain from known organic etiologies, such as back pain, diabetic neuropathy or rheumatoid arthritis.

Importance for Internists:

- A coordinated multidimensional intervention with behavioral, pharmacological and physical interventions is useful to improving mental health and functional outcomes in primary care patients with chronic pain.
- Emphasis should be placed on use of full dose antidepressants in these patients.

Background:

- To improve pain management, the Veterans Health Administration launched the “Pain as the 5th Vital Sign” initiative in 1999, requiring a pain intensity rating (0 to 10) at all clinical encounters.

Aims/purpose:

- To measure the initiative’s impact on the quality of pain management.

Methods:

- Retrospective review of medical records at a single medical center to compare providers’ pain management before and after implementing the initiative.
- Unique patient visits selected from all 15 primary care providers of a general medicine outpatient clinic.
- Used 7 process indicators of quality pain management, based on appropriately evaluating and treating pain, to assess 300 randomly selected visits before and 300 visits after implementing the pain initiative.
- Performed a subgroup analysis of patients reporting substantial pain (≥ 4) during a post-implementation visit.

Results:

- The quality of pain care was unchanged between visits before and after the pain initiative ($P > .05$ for all comparisons): subjective provider assessment (49.3% before, 48.7% after), pain exam (26.3%, 26.0%), orders to assess pain (11.7%, 8.3%), new analgesic (8.7%, 11.0%), change in existing analgesics (6.7%, 4.3%), other pain treatment (11.7%, 13.7%), or follow-up plans (10.0%, 8.7%).
- Patients ($n = 79$) who reported substantial pain often did not receive recommended care: 22% had no attention to pain documented in the medical record, 27% had no further assessment documented, and 52% received no new therapy for pain at that visit.

Author conclusions:

- Routinely measuring pain by the 5th vital sign did not increase the quality of pain management.
- Patients with substantial pain documented by the 5th vital sign often had inadequate pain management.

Importance for internists:

- Additional interventions are needed to improve providers’ awareness of patients’ pain and to increase the rates at which they provide appropriate therapy

Background:

- Multiple guidelines emphasize necessity of using pain assessment scales but no study has assessed impact of using these scales

Aims/Purpose:

- Assess impact of using pain assessment scale on level of pain relief obtained and physician prescribing practices

Methods:

- Randomized control, multi-center trial
- N = 772 general practice patients in France
- Endpoints = patient level of pain relief, physician prescription use
- Scales were visual analog scale (VAS) and an anxiety and depression scale (HAD)
- Scales administered to intervention group at initial and follow up visit one month later and to follow up group after first two visits

Results:

- Percentage of relief in non-scale, control group was actually significantly more (50.7%) than in intervention group (41.1%)
- After second visit significant decrease in level painkiller prescriptions in scale group

Author conclusions:

- Use of pain scales may alter patient's perception of pain
- Pain scale results may have made physicians more conservative about prescribing
- Physician decrease in prescribing practices in the scale group may have resulted in less pain relief for patients in this group
- Cannot say whether differences in pain relief between two groups existed prior to study since both groups could not be assessed (other than similarity in baseline characteristics)

Background:

- Chronic pain is often seen in the primary care setting often associated with mental health conditions.

Aims/Purpose:

- Primary care doctors should be able to integrate and coordinate care in patients with mental health and primary care.

Results:

- Stepped care should be considered in treating patients.
- Step 1 involves identifying and addressing specific patient concerns while enhancing patient readiness for self-care through motivational interviewing.
- Step 2 includes identifying specific patient difficulties, developing and implementing an individually tailored treatment plan and providing support/follow-up through psychologist.
- Step 3 often involves extensive involvement of mental health professionals

Author Conclusions:

- Treatment of pain often involves integration of pain treatment, a stepped-care approach, utility of a multidisciplinary team which is focused around the importance of the PCP.

Section 4: Pharmacologic Modalities for Pain

Comparative Effectiveness and Safety of Analgesics for Osteoarthritis: Comparative Effectiveness Review No. 4. Chou R et al. Agency for Healthcare Research and Quality September 2006; Available at www.effectivehealthcare.ahrq.gov/reports/final.cfm

Background:

- Many non-opioid medications are used to treat osteoarthritis with various effectiveness and side effects

Aims:

- To review the evidence behind NSAIDS, COX-2's, Tylenol, Glucosamine/Chondroitin and topical agents for osteoarthritis

Results:

- Good evidence that COX-2, and nonselective NSAIDS are comparable in efficacy, and Acetaminophen modestly inferior.
- Fair evidence that Gluc/Chondroitin is not more effective than placebo
- Good evidence that topical NSAIDS are comparable to oral NSAIDS.
- Good evidence that misoprostol or PPIs attenuate GI risk for NSAIDS, but use with anticoagulants increases GI bleeding risk 3 to 6 fold.
- Good evidence that COX-2 decrease serious GI events, but are at increased risk of serious CV events.
- Good evidence concomitant use of aspirin eliminates the GI benefits of COX-2

Author Conclusions:

- All non-opioid analgesics each have a unique set of risks and benefits. No current available analgesic offers a clear advantage. Patient factors such as age, CV risk, co-morbid, and concomitant medications should be considered.

Background:

- Opioid dependence is often treated with opioid agonist therapy (OAT). These patients may still develop acute painful conditions

Aims:

- To discuss the challenges in management of acute pain for patients already on opioid agonists.

Methods:

- Evidenced based review of literature.

Results:

- Multiple misconceptions can occur:
- The maintenance opioid agonist provides analgesia
- The use of opioids for analgesia may result in addiction relapse
- The additive effects of opioids and maintenance opioids may cause respiratory and CNS depression,
- Reporting pain may be a manipulation to obtain opioid medications, or drug-seeking, because of opioid addiction.

Author Conclusions:

- Patients on chronic opioid agonists have many neurophysiologic, behavioral, and social issues along with altered issues of tolerance and hyperalgesia that make acute treatment difficult.
- However, uninterrupted OAT and aggressive pain management will mitigate anxiety and facilitate successful treatment of pain.

Background:

- Neuropathic pain is difficult to treat and may need a combination of medications

Aims:

- Evaluate the efficacy of combination gabapentin and morphine for the treatment of diabetic neuropathy or postherpetic neuralgia

Methods:

- Randomized, double-blind, active placebo, crossover. Outcomes of pain intensity, McGill Pain questionnaire, adverse effects, mood and quality of life in 41 patients each over a 5 week period

Results:

- Morphine+Gabapentin produced lower pain scores (3.06 vs 3.70 morphine, 4.15 gabapentin, 4.49 placebo, and 5.72 baseline), as well as better McGill scores (7.5 versus 10.7 morphine, 10.7 gabapentin, 14.4 placebo), $p < 0.05$ for both comparisons.
- Combination therapy also improved Brief Pain inventory scores, SF-36 health scores and Beck Depression inventory scores compared with placebo (similar to individual treatments with morphine or gabapentin).

Author Conclusions:

- Gabapentin and Morphine achieved better analgesia at lower doses of each drug than either as a single agent over a 5 week period.

Importance for Internists:

- The use of gabapentin and morphine together may have a beneficial, superior, additive interaction in the treatment of neuropathic pain.

Background:

- Newer agents are being developed in the treatment of neuropathic pain

Aims:

- To evaluate the efficacy of duloxetine, a dual serotonin (5-HT) and norepinephrine (NE) in the treatment of diabetic neuropathy

Methods:

- Double blind, placebo, randomized 12 week trial in 334 patients
- Primary outcome is weekly mean score
- Secondary outcomes PGI-Improvement scale, BPI, CGI-Severity, Short-form McGill, and Hamilton Depression rating scale, and SF-36

Results:

- Patients in both duloxetine arms had a decrease in mean pain at 12 weeks, (-1.32, 95%CI -1.95 to -0.69 for 60mg daily) when compared to placebo.
- Significant changes also seen in the secondary measures except for Hamilton depression rating and dynamic allodynia.
- Patients on duloxetine also used less concomitant acetaminophen during the study.
- Nausea, dizziness, and fatigue were most common side effects.

Author Conclusions:

- Efficacy of duloxetine at 60mg daily and BID were similar, and both were better than placebo in multiple comparisons regarding diabetic neuropathic pain.

Importance for Internists:

- Duloxetine is another option in treating diabetic neuropathic pain.

Section 5: Interventional Modalities for Pain

Surgical and Nonoperative Treatment for Lumbar Disk Herniation: The Spine Patient Outcomes Research Trial (SPORT): A Randomized Trial. Weinstein JN, et al. JAMA 2006; 296(20):2441-50.

Background:

- Lumbar discectomy for back and leg symptoms is extremely common but efficacy remains controversial

Aims/Purpose:

- Assess efficacy of surgery for lumbar intervertebral disc herniation

Methods:

- 13 multi-disciplinary spine clinics in 11 US states
- N = 501 adult, surgical candidates with imaging confirmed intervertebral disc herniation and signs and symptoms of radiculopathy for at least 6 weeks, 94% completed at least one follow up visit and were included in analysis
- Interventions were standard open discectomy vs nonoperative treatment individualized to the patient
- Primary outcomes were changes from baseline on SF-36 health survey pain and physical function scales on modified Oswestry disability index at 6 weeks, 3 months, 6 months and 1 and 2 years from enrollment
- Secondary outcomes were sciatica severity on Sciatica Bothersomeness Index, satisfaction, self-reported improvement and employment status
- Intention to treat analysis performed for randomized cohort but also estimated an “as-treated” longitudinal analysis based on comparisons of those actually treated surgically and non-operatively

Results:

- Adherence to treatment was limited and there was significant crossover between groups (50% of surgery group and 30% of non-operative group received surgery within 3 months of enrollment)
- Intention to treat analysis demonstrated between-group differences in improvement which were consistently in favor of surgery although not statistically significant for primary endpoints
- Intention to treat analysis of secondary outcomes did show statistically significant differences for self rated progress and sciatica bothersomeness
- As-treated analyses showed strong, statistically significant advantages for surgery at all follow up times

Author conclusions:

- Due to large numbers of patients who crossed over in both directions conclusions based on intention-to-treat analysis regarding superiority of one approach over the other cannot be made
- Large effects seen in the as-treated analysis and characteristics of crossover patients suggests that intention to treat analysis underestimates effect of surgery

Surgical and Nonoperative Treatment for Lumbar Disk Herniation: The Spine Patient Outcomes Research Trial (SPORT) Observational Cohort. Weinstein JN, et al. JAMA 2006;296(20):2451-9.

Methods:

- Prospective observational cohort of patients (N = 743) meeting same criteria as SPORT randomized cohort but declining randomization
- 521 of these patients chose surgery and of these 91% had received surgery by 6 weeks of enrollment, 222 chose non-operative management and of these only 2% received surgery
- 97% completed at least one follow up visit and were included in the analysis
- Intervention and Outcomes same as SPORT randomized trial

Results:

- Treatment effects were statistically significant in favor of surgery for both primary and secondary outcomes at all time points
- Patients in observational cohort were relatively more symptomatic and functionally impaired than those in the randomized trial although absolute differences were small
- Patients in observational cohort had significantly greater perception that the problem was getting worse

Author Conclusions:

- Patients choosing operative intervention reported greater improvement than those choosing non-operative care
- Must interpret nonrandomized outcomes cautiously

Assessment: Use of Epidural Steroid Injections to Treat Radicular Lumbosacral Pain: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Armon C, et al. Neurology 2007;68;723-729.

Background:

- Epidural corticosteroid injections to treat sciatica date back to the 1950s and their use has increased over time despite conflicting reviews of efficacy and safety.

Aims/purpose:

- To determine the evidence to support use of epidural steroid injections in radicular lumbosacral pain to produce pain relief.

Methods:

- Medline searches were conducted in April 2003 and February 2005 using combinations of the terms “epidural injections” or “epidural steroids,” “double-blind,” “placebo-controlled,” and “radiculopathy.”
- A search of the Cochrane database of systematic reviews found no review on the use of epidural steroid injections to treat radicular pain.
- Review articles were scanned for additional articles meeting the inclusion criteria: none were found. Articles identified by reviewers of earlier versions of the manuscript were considered also.
- A separate Medline search using the key words “epidural steroid” and “complications” was performed to identify reported complications with the procedure.
- Results from selected articles and from the efficacy studies selected for inclusion were summarized.

Results:

- Epidural steroid injections may result in some improvement in radicular lumbosacral pain when assessed between 2 and 6 weeks following the injection, compared to control treatments.
- Epidural steroid injection for radicular lumbosacral pain does not impact average impairment of function, need for surgery, or provide long-term pain relief beyond 3 months.

Author Conclusions:

- The routine use of epidural steroid injections for radicular lumbosacral pain routine use is not recommended.
- There is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain.

Importance for Internists:

- Internists should be judicious in their referrals to anesthesiology based pain clinics that focus predominantly on interventions rather than a multi-disciplinary approach.

Section 6: Complementary and Alternative Medicine Modalities for Pain

Acupuncture in Patients with Chronic Low Back Pain: A Randomized Controlled Trial. Brinkhaus B et al. Archives of Internal Medicine. 2006; 166:450-457.

Background:

- One third of adults with low back pain in the United States were treated by a complementary and alternative medicine provider.
- Among the CAM treatment strategies, acupuncture is used frequently in patients with low back pain although its effectiveness is unclear.

Aims/purpose:

- To investigate the efficacy of acupuncture compared with minimal acupuncture and with no acupuncture in patients with chronic low back pain.

Methods:

- The Acupuncture Randomized Trial in Low Back Pain was a randomized, controlled, multicenter trial comparing acupuncture with minimal acupuncture and with a no acupuncture waiting list control. Minimal acupuncture (superficial needling at nonacupuncture points) served as a sham intervention.
- In the acupuncture and minimal acupuncture groups, patients were blinded with regard to treatment
- Patients were randomized in a 2:1:1 (acupuncture–minimal acupuncture–waiting list) ratio using a centralized telephone randomization procedure.
- Outcome measure: All patients completed a modified version of the pain questionnaire published by the German Society for the Study of Pain at baseline and after 8, 26, and 52 weeks
- 298 patients (146 in the acupuncture group, 73 in the minimal acupuncture group, and 79 in the waiting list group) were studied

Results:

- In the present study, acupuncture was more effective than no acupuncture in patients with chronic low back pain. Most outcome variables tended to be slightly better in the acupuncture group compared with the minimal acupuncture group.

Author Conclusions:

- Findings provide further evidence that patient with chronic low back pain who receive acupuncture experience clinically relevant benefits compared with patients receiving no acupuncture treatment.
- The correct location of needles plays only a limited role.

Importance for Internists:

- One of the largest and most rigorous trials to investigate the efficacy of acupuncture for low back pain
- Acupuncture is used frequently in patients with low back pain
- Acupuncture was more effective than no acupuncture in patients with chronic low back pain

Background:

- The dietary supplements glucosamine and chondroitin sulfate have been advocated, as safe and effective options for the management of symptoms of osteoarthritis.
- Analgesics as well as traditional and COX 2 NSAIDs have suboptimal effectiveness and their safety is questioned.
- A meta-analysis evaluating the efficacy of these supplements for osteoarthritis suggested potential benefit from these agents but questioned the scientific quality of the studies.

Aims/purpose:

- To evaluate rigorously the efficacy and safety of glucosamine, chondroitin sulfate, and the two in combination in the treatment of pain due to knee osteoarthritis.

Methods:

- The Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) is a randomized, double-blind, placebo- and celecoxib controlled, multicenter trial
- Eligible patients were randomly assigned with the use of a double-dummy scheme to one of five orally administered treatments: 500 mg of glucosamine hydrochloride three times daily, 400 mg of sodium chondroitin sulfate three times daily, 500 mg of glucosamine plus 400 mg of chondroitin sulfate three times daily, 200 mg of celecoxib (Celebrex, Pfizer) daily, or placebo.
- The primary outcome measure was a response to treatment.

Results:

- A total of 1583 patients underwent randomization
- As compared with the rate of response to placebo (60.1 percent), the rate of response to glucosamine was 3.9 percentage points higher ($P = 0.30$), the rate of response to chondroitin sulfate was 5.3 percentage points higher ($P = 0.17$), and the rate of response to combined treatment was 6.5 percentage points higher ($P = 0.09$). The rate of response in the celecoxib control group was 10.0 percentage points higher than that in the placebo control group ($P = 0.008$). For patients with moderate-to-severe pain at baseline, the rate of response was significantly higher with combined therapy than with placebo (79.2 percent vs. 54.3 percent, $P = 0.002$).

Author Conclusions:

- Overall, glucosamine and chondroitin sulfate were not significantly better than placebo in reducing knee pain by 20 percent.

Importance for Internists:

- Osteoarthritis is the most common form of arthritis in the United States and has a major effect on the health-related quality of life.
- In the United States, glucosamine and chondroitin sulfate are considered dietary supplements and are not held to the stringent standards of pharmaceutical manufacture.
- In making therapeutic decisions, physicians and patients alike should be aware that celecoxib has a much faster time to response than glucosamine, chondroitin sulfate, or the two in combination.
- Continuing research is needed

Background:

- There is evidence that acupuncture useful in improving function and reducing pain in patients with OA of the knee.
- Little information about the effectiveness of acupuncture treatment provided as an adjunct to routine medical care.

Aims/purpose:

- To investigate the effectiveness of acupuncture in addition to routine care compared with routine care alone, in the treatment of patients with chronic pain due to OA of the knee or hip pain.

Methods:

- The Acupuncture in Routine Care (ARC) study included a multi center, randomized controlled trial and a nonrandomized cohort.
- Only needle acupuncture was allowed.
- The primary outcome measure was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and secondary outcome measures were the percent reduction in the WOMAC index and the SF-36 component scales

Results:

- A total of 3,633 patients with pain due to arthritis of the knee or the hip were recruited for the study, data were available on 93.2% of the patients (308 in the randomized acupuncture group, 289 in the control group, 2,716 in the nonrandomized acupuncture group).
- OA of the knee was present in 57.1% of the patients, OA of the hip in 14.5%, and OA of both the knee and the hip in 28.4%.
- Most patients (76.6%) underwent 5-10 sessions
- The 3-month percent reduction in the WOMAC index was significantly more pronounced in the acupuncture group than in the control group, in the total study population as well as in the hip OA patients and the knee OA patients analyzed separately and for quality of life as assessed by both SF-36 component scores, with the mental component score in hip OA patients being the only exception.
- There were no differences between the acupuncture and control groups with regard to the proportion of patients prescribed

Author Conclusions:

- Patients with chronic pain due to OA of the knee or the hip who were treated with acupuncture in addition to routine care showed significant improvements in symptoms and quality of life compared with routine care alone.
- Physician characteristics, such as the level of formal acupuncture training or certification, did not influence treatment outcomes.

Importance for Internists:

- In patients with chronic pain due to OA of the knee or hip who were receiving routine primary care, addition of acupuncture to the treatment regimen resulted in a clinically relevant and persistent benefit.
- Acupuncture should be considered as a treatment option for patients with knee or hip OA-associated chronic pain.

Background:

- Despite the popularity of acupuncture, evidence of its efficacy for reducing pain remains equivocal.

Aims/purpose:

- To assess the efficacy and safety of traditional Chinese acupuncture (TCA) compared with sham acupuncture (needling at defined nonacupuncture points) and conservative therapy in patients with chronic pain due to osteoarthritis of the knee.

Methods:

- Randomized, controlled trial.
- Setting: 315 primary care practices staffed by 320 practitioners with at least 2 years' experience in acupuncture.
- Studied 1007 patients who had had chronic pain for at least 6 months due to osteoarthritis of the knee (American College of Rheumatology [ACR] criteria and Kellgren–Lawrence score of 2 or 3).
- Interventions: Up to 6 physiotherapy sessions and as-needed antiinflammatory drugs plus 10 sessions of TCA, 10 sessions of sham acupuncture, or 10 physician visits within 6 weeks. Patients could request up to 5 additional sessions or visits if the initial treatment was viewed as being partially successful.
- Measurements: Success rate, as defined by at least 36% improvement in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score at 26 weeks. Additional end points were WOMAC score and global patient assessment.

Results:

- Success rates were 53.1% for TCA, 51.0% for sham acupuncture, and 29.1% for conservative therapy.
- Acupuncture groups had higher success rates than conservative therapy groups (relative risk for TCA compared with conservative therapy, 1.75 [95% CI, 1.43 to 2.13]; relative risk for sham acupuncture compared with conservative therapy, 1.73 [CI, 1.42 to 2.11]).
- There was no difference between TCA and sham acupuncture (relative risk, 1.01 [CI, 0.87 to 1.17]).

Author conclusions:

- Compared with physiotherapy and as-needed antiinflammatory drugs, addition of either TCA or sham acupuncture led to greater improvement in WOMAC score at 26 weeks.
- No statistically significant difference was observed between TCA and sham acupuncture, suggesting that the observed differences could be due to placebo effects, differences in intensity of provider contact, or a physiologic effect of needling regardless of whether it is done according to TCA principles.

Importance for internists:

- Acupuncture may have a role in the multimodal treatment for pain and functional limitations from osteoarthritis of the knee

Randomized Controlled Trial of a Short Course of Traditional Acupuncture Compared with Usual Care for Persistent Non-Specific Back Pain. Thomas KJ et al. BMJ 2006;333:611-2.

Background:

- Non-specific low back pain is recurrent and associated with high health, social, and economic costs.
- Cochrane reviews exist for 13 different non-surgical treatments for back pain, including acupuncture
- Evidence is inconclusive and the best way to manage back pain remains unclear

Aim/purpose:

- To determine whether a short course of traditional acupuncture improves longer term outcomes for patients with persistent non-specific back pain in primary care

Methods:

- Open randomized controlled trial
- Setting: 3 private acupuncture clinics and 18 general clinics in York, England
- N = 241 randomized; adults 18-65 years of age with non-specific low back pain for 4 to 52 weeks
- 10 individualized acupuncture treatments over 3 months from qualified acupuncturists
- 160 intervention patients, 81 controls
- Patients in intervention also received massage, diet advice, and exercise
- Usual care = exercise, medications, PT or manipulations
- Outcome: Pain according to SF-36 bodily pain scale

Results:

- No differences in pain or function at 12 months
- Acupuncture group did show statistically significant improvement in SF-36 pain at 24 months compared to usual care group
- All groups has clinically significant improvements (i.e. SF-36 score > 5)
- Patients in acupuncture arm more likely to be "very satisfied" with their treatment compared to usual care
- Patients in acupuncture group less pain medication use

Authors conclusions:

- Weak evidence was found of an effect of acupuncture on persistent non-specific low back pain at 12 months
- Stronger evidence of a small benefit at 24 months

Importance for internists:

- Referral to a qualified traditional acupuncturist for a short course of treatment seems safe and acceptable to patients with low back pain