FLORIDA ORTHOPAEDIC INSTITUTE

USF HEALTH

THE OPIOID EPIDEMIC

IMPACT ON ORTHOPAEDIC SURGERY

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ORTHOPAEDIC TRAUMA SERVICE

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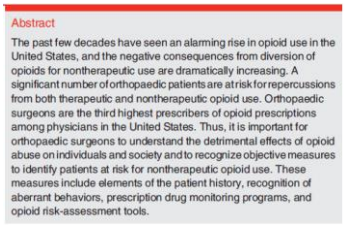
Orthopaedic Advances

Journal of the American Academy of Orthopaedic Surgeons

The Opioid Epidemic: Impact on Orthopaedic Surgery

Brent J. Morris, MD
Hassan R. Mir, MD, MBA, FACS

May 2015, Vol 23, No 5


Abstract

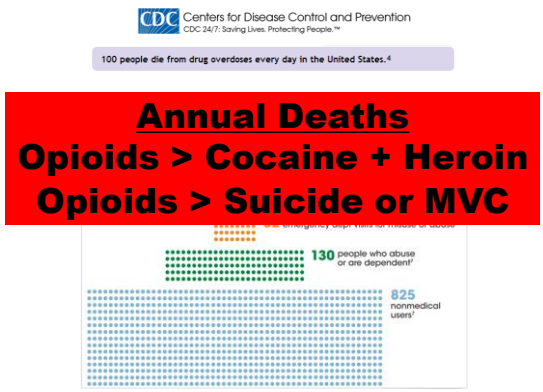
The past few decades have seen an alarming rise in opioid use in the United States, and the negative consequences from diversion of opioids for nontherapeutic use are dramatically increasing. A significant number of orthopaedic patients are at risk for repercussions from both therapeutic and nontherapeutic opioid use. Orthopaedic surgeons are the third highest prescribers of opioid prescriptions among physicians in the United States. Thus, it is important for orthopaedic surgeons to understand the detrimental effects of opioid abuse on individuals and society and to recognize objective measures to identify patients at risk for nontherapeutic opioid use. These measures include elements of the patient history, recognition of aberrant behaviors, prescription drug monitoring programs, and opioid risk-assessment tools.

Opioid Epidemic

- Americans <5% of World Population
  - **99% of Global Hydrocodone Supply**
  - **80% of Global Opioid Supply**
- Prescription Opioid Overdose Deaths Tripled in Last Decade

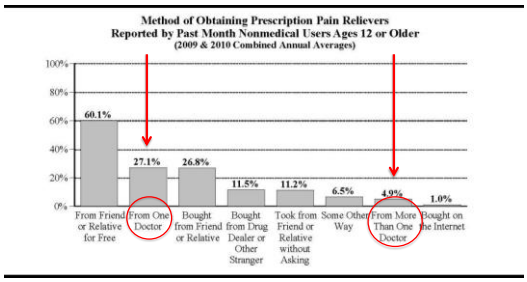
Manchikanti L, Singh Angelie. Therpeutic Opioids: a ten-year perspective on the complexities and complications of the escalating use, abuse, and nonmedical use of Opioids. *Pain Physician.* 2008;11:S63-S88.

CDC Press Release. Prescription painkiller overdoses at epidemic levels.

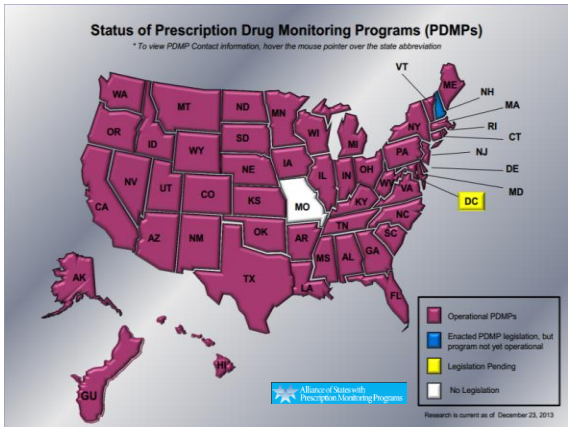


Annual Deaths
Opioids > Cocaine + Heroin
Opioids > Suicide or MVC

Source of Opioids?



Substance Abuse and Mental Health Services Administration (2007). Results from the 2006 National Survey on Drug Use and Health: National Findings. (Office of Applied Studies, NSDUH Series H-32, DHHS Publication No. SMA 07-4293). Rockville, MD. www.oas.samh sa.gov/nsduh/2k6nsduh/2k6results.pdf



States Requiring PDMP Use

Kentucky
Massachusetts
New Mexico
New York
Ohio
Tennessee
West Virginia

Role of Orthopaedic Surgeons?

Orthopedic Surgeons are the 3rd Highest Prescribers of Opioids

(7.7% of all Rx)

PCPs – 28.8%; Internists – 14.6%

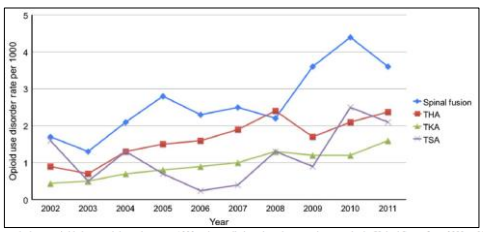
Orthopedic Surgery & Opioids

- Literature on Worse Clinical Outcomes in:
  - Trauma
  - Low Back Pain
  - Occupational MSK Disorders
  - TKA
  - Reverse Shoulder Arthroplasty
  - Spine Surgery
  - More coming…

Preoperative Opioid Misuse is Associated With Increased Morbidity and Mortality After Elective Orthopaedic Surgery

Mariano E. Menendez MD, David Ring MD, PhD, Brian T. Bateman MD, MSc

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons™
Volume 473, Number 7, July 2015



The graph shows opioid abuse and dependence per 1000 orthopaedic inpatients by procedure type in the United States from 2002 to 2011.

Conclusion Opioid abuse and dependence are increasing rapidly among orthopaedic surgical inpatients and are associated with considerable postoperative morbidity and mortality and resource utilization. We recommend that

Rates of Prescription Opiate Use Before and After Injury in Patients with Orthopaedic Trauma and the Risk Factors for Prolonged Opiate Use

Joel E. Holman, MD, Gregory J. Stoddard, MPH, and Thomas F. Higgins, MD

The Journal of Bone & Joint Surgery · jbjs.org
Volume 95-A · Number 12 · June 19, 2013

TABLE IV Duration of Use by Location of Injury

Type of Surgery	No. of Patients	Less Than Six Weeks	Between Six and Twelve Weeks	More Than Twelve Weeks
Upper-extremity surgery	68 (11.1%)	51 (75.0%)	9 (13.2%)	8 (11.8%)
Lower-extremity surgery	470 (76.7%)	325 (69.1%)	53 (11.3%)	92 (19.6%)
Pelvic or acetabular surgery	75 (12.2%)	43 (57.3%)	11 (14.7%)	21 (28.0%)

Conclusions: Patients with orthopaedic trauma are significantly more likely than the general population to use prescription opiates prior to injury. Preinjury opiate use is predictive of prolonged use postinjury and predictive of patients who will seek opiates from other providers.

Narcotic Use and Postoperative Doctor Shopping in the Orthopaedic Trauma Population

Brent J. Morris, MD, Justin W. Zumsteg, MD, Kristin R. Archer, PhD, Brian Cash, BS, and Hassan R. Mir, MD

The Journal of Bone & Joint Surgery · jbjs.org
Volume 96-A · Number 15 · August 6, 2014

Orthopaedic Trauma Patients using Opioids Preoperatively?

Doctor Shopping Postoperatively?

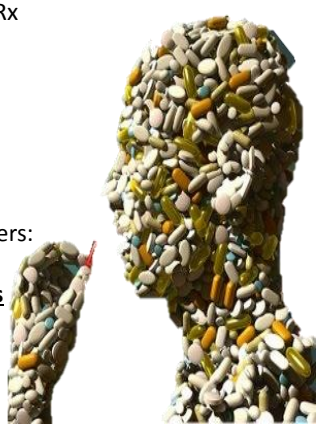
Doctor Shopping

- Prevalence: **21%**

Increased:
– Postop Opioid Rx
– Duration of Postop Opioid Use
– MED per day

Rx

- Single Opioid Provider:
  - –**2 Rx's**
  - –Duration of **28 days**
  - –**26 MED/day (mg)**
- Multiple Opioid Providers:
  - –**7 Rx's**
  - –Duration of **110 days**
  - –**43 MED/day (mg)**



Doctor Shopping Predictors

- **≤High School Education (3.2 X)**
- **Preoperative Opioid Use (4.5 X)**

Recommendations

- Monitor Postoperative Opioid Rx following Orthopaedic Trauma
- Identify and Prevent Doctor Shopping
  - CSMD Utilization
  - Particularly for Patients with:
    - Lower Level of Education
    - History of Preoperative Opioid Use

Identifying the At-risk Patient

Risk factors for nontherapeutic opioid use
- Personal or family history of substance abuse
- Nicotine dependency
- Age <45 yr
- History of depression or other psychiatric diagnoses (eg, schizophrenia, bipolar disorder)
- Lower level of education
- History of preinjury/preoperative opioid use

Aberrant behavior monitoring
- Early refill requests
- Treatment noncompliance
- Reports of "lost or stolen" prescriptions

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Risk Factors for Continued Opioid Use One to Two Months After Surgery for Musculoskeletal Trauma

Gijs T.T. Helmerhorst, MD, Ana-Maria Vranceanu, PhD, Mark Vrahas, MD, Malcolm Smith, MD, and David Ring, MD, PhD

THE JOURNAL OF BONE & JOINT SURGERY · JBJS.ORG
VOLUME 96-A · NUMBER 6 · MARCH 19, 2014

Methods: Operatively treated patients (n = 145) with musculoskeletal trauma were evaluated one to two months after surgery. Patients indicated if they were taking opioid pain medication and completed several psychological questionnaires: the Center for Epidemiologic Studies Depression Scale, the Pain Catastrophizing Scale, the Pain Anxiety Symptoms Scale, and the Posttraumatic Stress Disorder Checklist, civilian version. The Numeric Rating Scale was used to measure pain intensity. Disability was measured with use of the Short Musculoskeletal Function Assessment Questionnaire and injury severity was measured with use of the Abbreviated Injury Scale.

Conclusions: Patients who continue to use opioid pain medication one to two months after surgery for musculoskeletal trauma have more psychological distress, less effective coping strategies, and greater symptoms and disability than patients who do not take opioids, irrespective of injury, surgical procedure, or surgeon.

Patient Expectations

Opioid Use After Fracture Surgery Correlates With Pain Intensity and Satisfaction With Pain Relief

Arjan G. J. Bot MD, PhD, Stijn Bekkers BSc, Paul M. Arnstein PhD, R. Malcolm Smith MD, David Ring MD, PhD

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®
Volume 472, Number 8, August 2014

Methods Ninety-seven inpatients completed measures of pain intensity (numeric rating scale), satisfaction with pain relief, self-efficacy when in pain, and symptoms of depression days after operative fracture repair. The amount of opioid used in oral morphine equivalents taken during the prior 24 hours was calculated. Through initial bivariate and then multivariate analysis, we identified factors that were associated with pain intensity, less than complete satisfaction with pain control, and less than complete satisfaction with staff attention to pain relief.

Conclusions After operative fracture treatment, patients who take more opioids report greater pain intensity and less satisfaction with pain relief. Greater self-efficacy was the best determinant of satisfaction with pain relief. Evidence-based interventions to increase self-efficacy merit additional study for the management of postoperative pain during recovery from a fracture.

Differences in Prescription of Narcotic Pain Medication After Operative Treatment of Hip and Ankle Fractures in the United States and the Netherlands

Anneluuk L. C. Lindenhovious, MSc, Gijs T. T. Helmerhorts, MSc, Alexandra C. Schnellen, MSc, Mark Vrahas, MD, David Ring, MD, and Peter Kloen, MD, PhD

The Journal of TRAUMA® *Injury, Infection, and Critical Care* • Volume 67, Number 1, July 2009

TABLE 3. Comparison of Narcotics Prescription Between Countries

	American	Dutch	*p*
Hip fractures			
Inpatient	85	58	<0.001
Outpatient	77	0	<0.001
Ankle fractures			
Inpatient	98	64	<0.001
Outpatient	82	6	<0.001

Conclusions: American patients are prescribed significantly more inpatient and outpatient narcotic pain medication than Dutch patients after operative treatment of hip and ankle fractures.

Classification Schedules for Controlled Substances

Schedule II prescriptions[a]
- Combination products containing hydrocodone plus acetaminophen, ibuprofen, or aspirin (Vicodin, Lortab, Norco)
- Immediate or sustained-release oxycodone (Percocet, OxyContin)
- Hydromorphone (Dilaudid)
- Immediate or sustained release morphine sulfate
- Codeine sulfate
- Methadone
- Meperidine (Demerol)
- Sublingual or transdermal fentanyl

Schedule III prescriptions[b]
- Combination products with up to 90 mg codeine plus acetaminophen, ibuprofen, or aspirin (Tylenol with Codeine)

[a] Require a written prescription for up to a 90-day supply, and each refill requires a new written prescription.
[b] Dispensed or refilled by written or verbal prescriptions.

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Example of a Postoperative Pain Management Protocol With an Opioid Taper Following Fracture Surgery

Time After Discharge	Dosage
First 2 wk after discharge: Oxycodone 10 mg	1 tablet every 4 to 6 h for 14 d
Week 3 (if necessary): Hydrocodone/acetaminophen 10/325 mg	1 or 2 tablets every 4 to 6 h for 7 d
Week 4 (if necessary): Hydrocodone/acetaminophen 7.5/325 mg	1 tablet every 6 hours for 7 d
Week 5 (if necessary): Hydrocodone/acetaminophen 5/325 mg	1 tablet every 8 hours for 7 d
Week 6 and beyond (if necessary)	Over-the-counter medications including acetaminophen and acetaminophen extra strength. Patients with fracture fixation may start NSAIDs at week 12 after surgery. Patients without fracture fixation may be started on NSAIDs immediately postoperatively.
If stronger pain medication is needed at 6 wk postoperatively or beyond: Tramadol 50 mg	1 tablet every 8 h for 14 d

NSAID = nonsteroidal anti-inflammatory drug

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Provider Education

Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000–2010

Matthew Daubresse, MHS† Hsien-Yen Chang, PhD,‡ Yuping Yu, PharmD,† Shilpa Viswanathan, MS,* Nilay D. Shah, PhD,§ Randall S. Stafford, MD, PhD,‖ Stefan P. Kruszewski, MD,¶# and G. Caleb Alexander, MD, MS*†***

Medical Care • Volume 51, Number 10, October 2013

Results: Primary symptoms or diagnoses of pain consistently represented one-fifth of visits, varying little from 2000 to 2010. Among all pain visits, opioid prescribing nearly doubled from 11.3% to 19.6%, whereas nonopioid analgesic prescribing remained unchanged (26%–29% of visits). One-half of new musculoskeletal

Conclusions: Increased opioid prescribing has not been accompanied by similar increases in nonopioid analgesics or the proportion of ambulatory pain patients receiving pharmacologic treatment. Clinical alternatives to prescription opioids may be underutilized as a means of treating ambulatory nonmalignant pain.

Provider Education

Rising Opioid Prescribing in Adult U.S. Emergency Department Visits: 2001–2010

Maryann Mazer-Amirshahi, PharmD, MD, Peter M. Mullins, MA, Irit Rasooly, John van den Anker, MD, PhD, and Jesse M. Pines, MD, MBA, MSCE

Results: Between 2001 and 2010, the percentage of overall ED visits (pain-related and non–pain-related) where any opioid analgesic was prescribed increased from 20.8% to 31.0%, an absolute increase of 10.2% (95% confidence interval [CI] = 7.0% to 13.4%) and a relative increase of 49.0%. Use of DEA schedule II analgesics increased from 7.6% in 2001 to 14.5% in 2010, an absolute increase of 6.9% (95% CI = 5.2% to 8.5%) and a relative increase of 90.8%. Use of schedule III through V agents increased from 12.6% in 2001 to 15.6% in 2010, an absolute increase of 3.0% (95% CI = 2.0% to 5.7%) and a relative increase of 23.8%. Prescribing of hydrocodone, hydromorphone, morphine, and oxycodone all increased significantly, while codeine and meperidine use declined. Prescribing of nonopioid analgesics was unchanged, 26.2% in 2001 and 27.3% in 2010 (95% CI = –1.0% to 3.4%). Hydromorphone and oxycodone had the greatest increase in ED administration between 2005 and 2010, while oxycodone and hydrocodone had the greatest increases in discharge prescriptions. There was no difference in discharge prescriptions for nonopioid analgesics. The percentage of visits for painful conditions during the period increased from 47.1% in 2001 to 51.1% in 2010, an absolute increase of 4.0% (95% CI = 2.3% to 5.8%).

Conclusions: There has been a dramatic increase in prescribing of opioid analgesics in U.S. EDs in the past decade, coupled with a modest increase in pain-related complaints. Prescribing of nonopioid analgesics did not significantly change.

Pain Clinics

- Rapid Rise in Number
- 732 in FL
  - 4 Pain Clinics for every 100,000 People
  - Outnumber McDonald's
- Some Pain Clinics provide Important Services for Patient Care and Pain Management
- However, "Pill Mills" Prescribe and Dispense Controlled Substances Outside the Scope of Standard Medical Practice

PDMPs

- Programs with Positive Early Results

> And it's had some quick success, Dr. Nirav Shah, commissioner of the state's Health Department, reported at a public hearing on the 2014-15 executive budget proposal. Calling I-STOP a "national model" for controlling substance abuse, he reported that there was a 74.9% decrease in doctor shopping in the fourth quarter of 2013 compared with the same period the previous year. The program went into effect in June 2013 and created a prescription-monitoring registry that includes real-time information from pharmacies on which controlled substances are being dispensed.

> Since August, more than 66,000 clinicians have run 7 million prescription checks on 2.9 million patients, according to a news release. I-STOP replaced an earlier program that was used by only 5,100 providers and monitored less than 466,000 patients in 3½ years.

Conclusions

- The US is in an Opioid Epidemic
  - Detrimental Effects on Individuals and Society
- Our Patients are At-Risk
  - Orthopaedic Surgeons should:
    - Recognize Risk Factors
    - Set Patient Expectations and Prescribe Responsibly
    - Take Control of MSK Pain Management
    - Educate Other Providers


THANK YOU
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ORTHOPAEDIC TRAUMA SERVICE
Hassan R. Mir, MD, MBA, FACS

Intravenous (IV) Acetaminophen Effectiveness in Pain Management of the Geriatric Hip Fracture Patient

Clifford B. Jones, MD FACS
The CORE Institute
Banner University Medical Center
University of Arizona Orthopaedic Residency Program
Phoenix AZ

Is Scheduled Intravenous Acetaminophen Effective in the Pain Management Protocol of Geriatric Hip Fractures?

Alexander J. Bollinger, M.D. [1,2]
Paul D. Butler, M.D. [1,2]
Matthew S. Nies, M.D. [2]
Debra L. Sietsema, PhD. [2,3]
Clifford B. Jones, M.D. [2,3]
Terrence J. Endres, M.D. [2,3]

American Academy of Orthopaedic Surgeons, Annual Meeting
March 24, 2015

Is Scheduled Intravenous Acetaminophen Effective in the Pain Management Protocol of Geriatric Hip Fractures?

Alexander J. Bollinger, MD[1,2], Paul D. Butler, MD[1,2], Matthew S. Nies, MD[3], Debra L. Sietsema, PhD[2,4], Clifford B. Jones, MD, FACS[2,4], and Terrence J. Endres, MD[2,4]

Geriatr Orthop Surg Rehabil. 2015 Sep;6(3):202-8. doi: 10.1177/2151458515588560.

Geriatric Orthopaedic Surgery & Rehabilitation
1-7

DOI: 10.1177/2151458515588560
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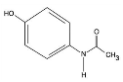
Purpose

- Hip fractures are a common problem in the geriatric population, having substantial impact on the healthcare system
  - $30 billion annual cost [1-2]
- Often result in functional decline and greater mortality [2-9]

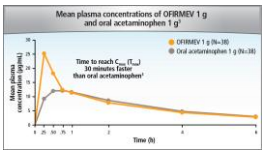
Purpose - con't

- Post-operative pain control remains difficult in the elderly population
  - Opioid- and NSAID-associated complications more common [2,10-22]
  - Intravenous acetaminophen has been shown in prior studies to be safe and efficacious in major orthopaedic surgery [20,22-29]

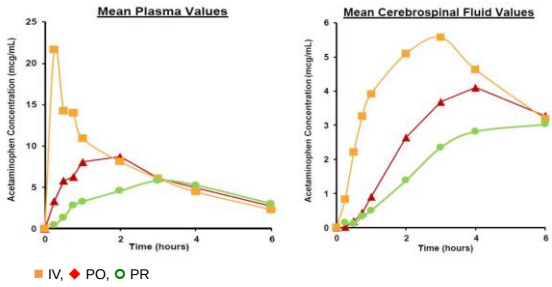


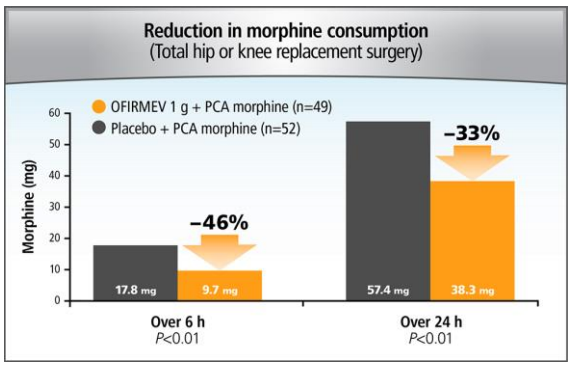
What is IV Tylenol

- OFIRMEV® (acetaminophen) injection
- Mallinckrodt Pharmaceuticals
- Administration 650mg q 4 or 1000mg q 6
- 70% Higher peak 15-30 min dose
- 50% Lower hepatic levels

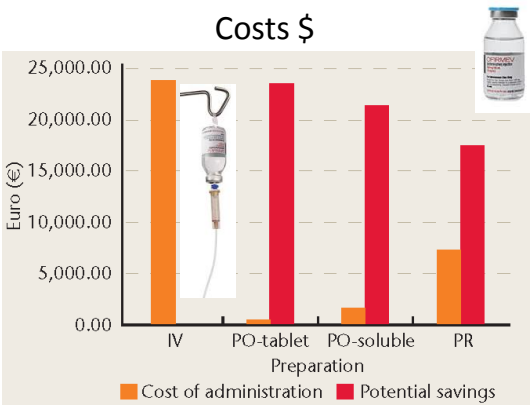


Mean Plasma & CSF Concentrations of IV, PO, & PR Acetaminophen





Costs $



Hypothesis

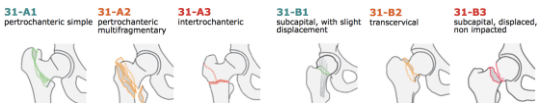
- The use of scheduled IV acetaminophen as part of a perioperative pain-control protocol for patients 65 or older with hip fractures will reduce problems associated with inadequate pain control, while simultaneously decreasing complications associated with opioid analgesic use and reducing length of hospital stay.
- Start on admission
- Complete POD #2

Methods

- Retrospective chart review from June 1, 2011 - May 31, 2013
  - Group 1: June 1, 2011 - May 31, 2012
    - (before initiation of protocol)
  - Group 2: June 1, 2012 - May 31, 2013
    - (after initiation of protocol)

Methods - con't

- Inclusion Criteria:
  - 65 years or older
  - Admitted to orthopaedic surgery service
  - Underwent operative fixation of "hip" fracture by one of six surgeons within specified time period
    - CPT codes 27235, 27236, 27244, 27245
    - AO classification 31-A & 31-B



Methods - con’t

– Exclusion Criteria:
- Pathologic fracture
- Periprosthetic fracture
- Concomitant orthopaedic injury requiring operative intervention
- Perioperative death (same hospitalization)

Methods - con't

	Total Fractures	Group 1	Group 2
Geriatric Fractures	433	214	219
Subtrochanteric	13	7	6
Non-Ortho Admit	55	24	31
Included Hip Fractures	365	183	182
Exclusions:			
Concomitant Injuries	8	3	5
Periprosthetic	8	5	3
Pathologic	8	4	4
Perioperative Death	5	2	3
Total	336	169	167

Methods - con’t

- Statistical Analysis
- Quantitative data were analyzed using the unpaired t-test, while nominal data were analyzed using the chi-square test
- Multivariate regression analyses for quantitative data and logistic regression analysis for nominal data
- Significance evaluated at $p<0.05$

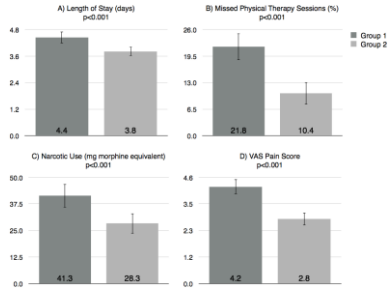
Study Population

	Group 1 (n=169)	Group 2 (n=167)	p-Value
Age (years)*	83.3 (65-101)	81.8 (66-101)	0.08
Gender (number of patients)			0.85
Male	45 (27%)	46 (28%)	
Female	124 (73%)	121 (72%)	
Fracture (number of patients)			0.33
Femoral Neck	81 (48%)	78 (47%)	
Intertrochanteric	88 (52%)	89 (53%)	
Surgical Treatment			0.81
Arthroplasty	71 (42%)	68 (41%)	
Internal Fixation	98 (58%)	99 (59%)	
Body Mass Index*	25.3 (13.4-57.1)	26.3 (16.1-41.5)	0.10
Time from Admission to OR (hours)*	17.1 (1-65)	15.3 (0-56)	0.09
Total Acetaminophen (# doses)*	8.7 (0-35)	9.2 (0-30)	0.48
Oral Acetaminophen (# doses)*	8.5 (0-35)	5.4 (0-27)	<0.001
IV Acetaminophen (# doses)*	0.2 (0-12)	3.7 (0-12)	<0.001

Results

	Group 1 (n=169)	Group 2 (n=167)	p-Value
Length of Stay (days)			<0.001
Mean (Range)	4.4 (1.2-13)	3.8 (1.5-11.4)	
Narcotic Use (mg morphine-equivalent)			<0.001
Mean (Range)	41.3 (0-189.7)	28.3 (0-204.3)	
Daily Narcotic Use (mg/day)			0.05
Mean (Range)	9.6 (0-49.9)	7.8 (0-53.2)	
Bowel Motility Agents (# doses)			0.29
Mean (Range)	1.0 (0-10)	0.8 (0-4)	
Anti-emetic Agents (# doses)			0.48
Mean (Range)	0.8 (0-11)	0.7 (0-7)	
Pain Score (VAS scale)			<0.001
Mean (Range)	4.2 (0-9.2)	2.8 (0-7.7)	
Missed PT sessions (%)			<0.001
Mean (Range)	21.8 (0-66.7)	10.4 (0-100)	
Discharge Location (# patients)			0.001
Home	12 (7%)	32 (19%)	
Secondary Care Facility	157 (93%)	135 (81%)	

Results - con't



Results - con't

Length of Stay

	Beta Coefficient	p-Value
Age	–	*0.07*
IV Acetaminophen	-0.581	*<0.001*
Sex	–	0.16
BMI	–	0.09
Time to OR	0.058	*<0.001*
Diagnosis	–	0.93
Narcotic Use	.009	*<0.001*
Pain Score	–	0.76

Results - con't

Pain Score

	Beta Coefficient	p-Value
Age	-0.028	*0.001*
IV Acetaminophen	-1.4	*<0.001*
Sex	–	0.94
BMI	–	0.84
Time to OR	–	0.94
Diagnosis	–	0.25
Narcotic Use	x	x
Pain Score	x	x

Results - con't

Narcotic Use

	Beta Coefficient	p-Value
Age	-1.01	*<0.001*
IV Acetaminophen	-16.23	*<0.001*
Sex	–	0.18
BMI	0.82	*0.001*
Time to OR	0.44	*0.01*
Diagnosis	–	0.71
Narcotic Use	x	x
Pain Score	x	x

Results - con't

Missed PT Sessions

	Beta Coefficient	p-Value
Age	–	0.49
IV Acetaminophen	-11.4	*<0.001*
Sex	–	0.74
BMI	–	0.17
Time to OR	–	0.71
Diagnosis	–	0.51
Narcotic Use	–	0.10
Pain Score	–	0.33

Results - con't

Regression Analysis: Odds of Discharge to Secondary Care Facility

Variable	Unit	OR (95% CI)	p-value
Age	One year of Increasing Age	1.1 (1.1-1.2)	*<0.001*
IV Acetaminophen	Use of IV Acetaminophen	0.45 (0.21-0.95)	*0.008*
Sex	Female Gender	2.1 (1.0-4.3)	*0.025*
BMI	N/A	–	0.54
Time to OR	One Hour of Increased Time to OR	1.1 (1.0-1.1)	*0.046*
Diagnosis	N/A	–	0.64
Narcotic Use	10 mg morphine-equivalent	1.2 (1.02-1.3)	*0.03*
Pain Score	N/A	–	0.45

Results - con't

- Intravenous acetaminophen usage both correlated with and was independently predictive of:

- shorter mean length of hospital stay
- lower mean narcotic usage
- lower mean pain score
- lower percentage of physical therapy sessions missed
- higher likelihood of discharge to home

Conclusion

- The utilization of scheduled IV acetaminophen as part of a standardized pain-management protocol for geriatric hip fractures resulted in a shortened length of hospital stay, decreased pain score and narcotic use, fewer missed physical therapy sessions, and higher rate of discharge to home.

Future Directions?

- Cost-analysis
  - OFIRMEV® ~$40 per 1000 mg dose
- Prospective, randomized trials
  - Verified outcome measures



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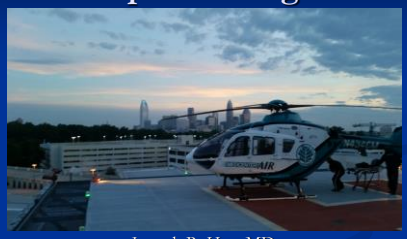
Thank You

Pain Strategies for Practicing Orthopaedic Surgeons



Joseph R. Hsu, MD
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Limb Lengthening and Deformity Service
Carolinas Medical Center

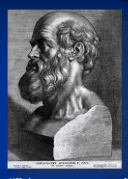
Disclosures

- CDC funding
  - Prescription Reporting with Immediate Medication Utilization Mapping (PRIMUM)
- Smith & Nephew – speakers bureau
- Acumed – consulting

Slide contributions from Michael Ruffolo, Steven Olson, and Alejandro Marquez-Lara

BLUF: Multi-modal strategy

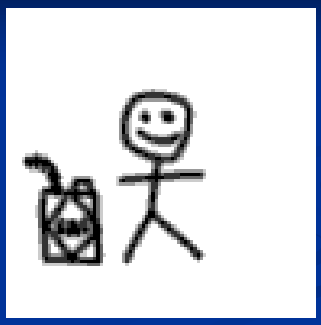
- Short acting opioids
  - 8 weeks maximum
    - Refer to pain management if requiring more narcotics
- NSAIDs
  - Non-selective:
    - Ibuprofen, naproxen, etc.
  - Selective if GI risk:
    - Meloxicam (generic)
- Gabapentin
  - Up to 1800 mg/day effective
  - Increased evening dose



"Primum non nocere"

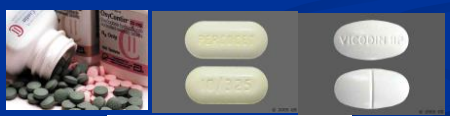
- No sustained-release opioids
- No sedative-hypnotics
  - Benzos, ambien, etc.

Did he say NSAIDS???



What should you fear?

Geusens P, Emans PJ, de Jong JJ, van den Bergh J. NSAIDs and fracture healing. Curr Opin Rheumatol. 2013 Jul;25(4):524-31.



Risk Factors for Continued Opioid Use One to Two Months After Surgery for Musculoskeletal Trauma

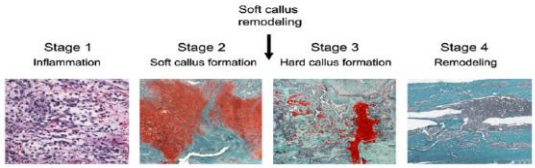
J Bone Joint Surg Am. 2014;96:495-9

Ortho influence on pain management

- Walter Crawford Kelly, Jr. (August 25, 1913 – October 18, 1973)

Why are we so convinced that NSAIDs are bad for musculoskeletal tissues?

Secondary Bone Healing

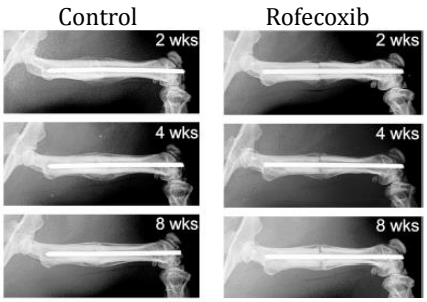


Schindeler et al, Stem Cell Dev Biology, 2008

PG →

Inflammation Vasodilation "4Rs"	Chondrocyte Activity	Osteoblast Activity	Angiogenesis

Secondary Bone Healing Models

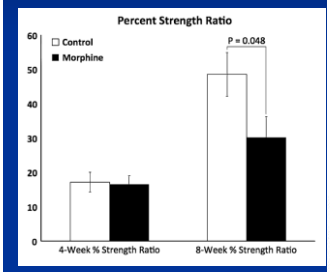


Simon AM., et al., JBMR, 2002

Postoperative Opioid Administration Inhibits Bone Healing in an Animal Model

Jesse Chrastil MD, Christopher Sampson BS, Kevin B. Jones MD, Thomas F. Higgins MD

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®
Clin Orthop Relat Res (2013) 471:4076–4081



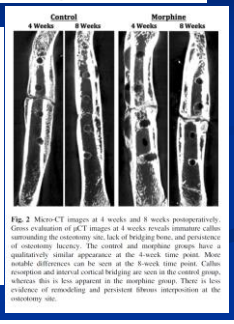
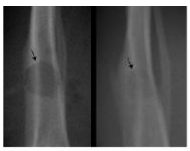


Fig. 2 Micro-CT images at 4 weeks and 8 weeks postoperatively. Gross evaluation of μCT images at 4 weeks reveals immature callus surrounding the osteotomy site, lack of bridging bone, and persistence of osteotomy lucency. The control and morphine groups have a qualitatively similar appearance at the 4-week time point. More notable differences can be seen at the 8-week time point. Callus resorption and interval cortical bridging are seen in the control group, whereas this is less apparent in the morphine group. There is less evidence of remodeling and persistent fibrous interposition at the osteotomy site.

Primary Bone Healing Models



Martins MV., et al., Braz Dent J, 2005

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NSAIDs do not appear to have a significant effect on primary bone healing

Significant flaws in clinical studies condemning NSAIDS

Burd TA, Hughes MS, Anglen JO. Heterotopic ossification prophylaxis with indomethacin increases the risk of long-bone nonunion. J Bone Joint Surg (Br) 2003;85(5):700-5.

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Giannoudis PV, MacDonald DA, Matthews SJ, Smith RM, Furlong AJ, De Boer P. Nonunion of the femoral diaphysis. The influence of reaming and non-steroidal antiinflammatory drugs. J Bone Joint Surg (Br) 2002;82(5):655-8.

Nonunion of the femoral diaphysis

THE INFLUENCE OF REAMING AND NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

P. V. Giannoudis, D. A. MacDonald, S. J. Matthews, R. M. Smith, A. J. Furlong, P. De Boer

From St James' University Hospital, Leeds and York District Hospital, York, England

JBJS Br, 2000

- Case-Control
  - 32 Nonunions of Femoral Diaphysis vs 67 Comparable patients
    - Sample size
- Patient recall phone or clinic
  - NSAID use cause or result of nonunion?
- NSAID Use
  - 62.5% vs 13.4%
  - 22 vs 1 week use
  - RR = 10.74
- Many different techniques: Different nails, reamed and unreamed.

Table IV. The effect of NSAIDs on the incidence of nonunion

	NSAIDs		
Group	**Yes**	**No**	**Total**
1	20	12	32
2	9	58	67

Table V. Predictors of primary interest for nonunion

Predictor	Odds ratio (95% CI)	p value
Reaming	1.83 (0.68 to 5.19)	0.275
Smoking	2.29 (0.85 to 6.08)	0.107
NSAIDs	10.74 (3.55 to 33.23)	0.000

Slide from Michael Ruffalo, MD

Nonsteroidal anti-inflammatory drugs' impact on nonunion and infection rates in long-bone fractures

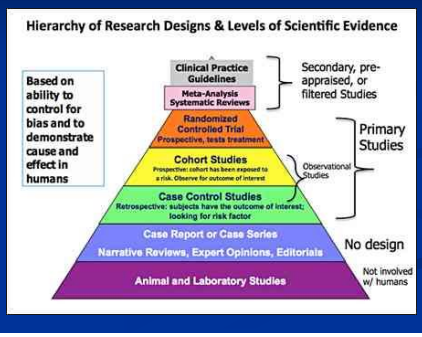
David R. Jeffcoach, MD, Valerie G. Sams, MD, Christy M. Lawson, MD, Blaine L. Enderson, MD, MBA, Scott T. Smith, MD, Heather Kline, PA-C, Patrick B. Barlow, BA, Douglas R. Wylie, PharmD, Laura A. Kromenacker, PharmD, James C. McMillen, PharmD, Jordan Pyda, BS, Brian J. Daley, MD, MBA, *and* University of Tennessee Medical Center, Department of Surgery, *Knoxville, Tennessee*

J Trauma Acute Care Surg, 2014

- Retrospective Case-Control of all femur, tibia, humerus fractures
- 1,901 Patients
  - 12.1% Received NSAIDS (short term in hospital)
- NSAIDS
  - 17% of patients receiving NSAIDS had a complication
  - OR = 2.17 p < 0.016
- No mention of NSAID use out of hospital
- No discussion of fracture characteristics
- Best Trauma Center in America?
  - <1% infection in open fractures
  - 3.2% Infection, Malunion/Nonunion Rate

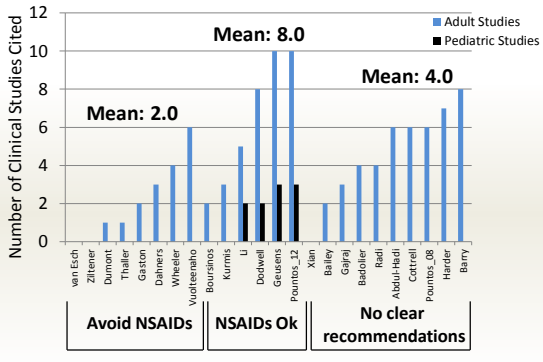
Slide from Michael Ruffalo, MD

Levels of evidence



Basic Science combined with clinical data

Literature Reviews



Clinical data only

Geusens et al Metabolic Bone Disease 2013

Table 2. Studies in humans on the effect of NSAIDs on fracture healing

References	Design	NSAID	Outcome
No effect			
Wurnig *et al.* [46]	Prospective	Indomethacin	Hip replacement: no effect on periprosthetic bone loss
Davis and Ackroyd [47]	RCT	Fluriprofen	Colles fracture
Adolphson *et al.* [48]	RCT	Piroxicam	Colles fracture
Sculean *et al.* [49]	RCT	Rofecoxib	Periodontal defects after periodontal surgery with enamel matrix proteins
Meunier *et al.* [50]	RCT	Celecoxib	Prosthesis migration, pain scores, range of motion, and subjective outcomes after total knee replacement
Vitale *et al.* [51]	Retrospective	Ketorolac	Reoperation after scoliosis surgery
Pradhan *et al.* [52]	Retrospective	Ketorolac (48 h)	Spinal fusion rate
Sucato *et al.* [53]	Retrospective	Ketorolac	Pseudoarthrosis after spinal fusion
Horn *et al.* [54]	Retrospective	Ketorolac	Nonunion after spinal fusion

OR, odds ratio; RCT, randomized-controlled trial; RR, relative risk.

General Review Pountous et al World J of Surg 2012

TABLE 3: The effect of NSAIDs on spinal fusion in humans.

Study/Year	Design	NSAID used	Conclusions and recommendations
Deguchi et al., 1998 [128]	Retrospective review of 73 patients undergoing primary or revision one or two level lumbar fusion	Not specified	(i) Patients who continued to take NSAIDs for more than 3 months postoperatively showed significantly lower fusion and success rates
Glassman et al., 1998 [129]	Retrospective review of 288 patients undergoing posterior L4 to sacral fusion	Ketorolac	(i) High rate of nonunion in spinal fusion (ii) Avoid NSAIDs in early postoperative period is recommended
Vitale et al., 2003 [130]	Retrospective review of 208 children undergoing scoliosis correction	Ketorolac	(i) No significantly increase in complications, including transfusion and reoperation
Park et al., 2005 [131]	Retrospective review of 88 consecutive patients undergoing posterolateral lumbar fusion	Ketorolac	(i) The incidence of incomplete union or nonunion was much higher in the ketorolac group, and the relative risk was approximately 6 times higher than control group
Pradhan et al., 2008 [132]	Retrospective review of 803 consecutive patients undergoing one, two or three level posterolateral lumbar fusion	Ketorolac	(i) The use of ketorolac limited to 48 hours after surgery for adjunctive analgesia, has no significant effect on ultimate fusion rates.
Sucato et al., 2008 [133]	Retrospective review of 319 patients undergoing scoliosis correction	Ketorolac	(i) Ketorolac does not increase the incidence of developing a pseudoarthrosis when used as an adjunct for postoperative analgesia
Lumawig et al., 2009 [134]	Retrospective review of 273 patients undergoing one or two level posterior lumbar fusion	Diclofenac	(i) Diclofenac sodium showed a dose-dependent inhibitory effect toward spinal fusion especially when used during the immediate postoperative period
Horn et al., 2010 [135]	Retrospective review of 46 pediatric patients who undergone spinal fusions for scoliosis	Ketorolac	(i) No clinical or radiographic evidence of curve progression, nonunion, or instrumentation failure

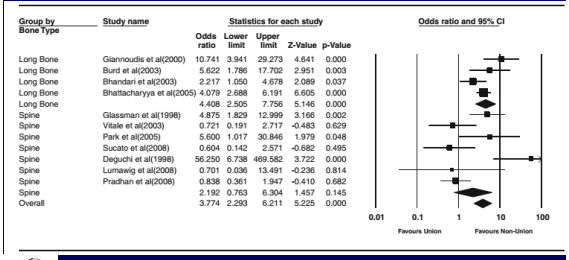
OTA

TABLE 4: Studies analyzing the effect of NSAIDs on f

The prospective series show less adverse effects

Study/Year	Design	NSAID used	
Davis and Ackroyd, 1988 [136]	Prospective double-blinded study of 100 patients with Colles' fracture	Fluriprophen (50 mg TDS)	(i) No effect on Colles' fracture.
Adolphson et al., 1993 [137]	Randomized double-blinded study on 42 postmenopausal women with colles fracture	Piroxicam	(i) No decrease of the rate of fracture healing (ii) Patients receiving piroxicam had significantly less pain (iii) No difference in the rate of functional recovery
Butcher and Marsh, 1996 [138]	Retrospective review of 94 patients with tibial fracture	Not specified	(i) Increase in the length of time to union by of 7.6 weeks ($P = 0.0003$) (16.7 weeks versus 24.3 weeks).
Wurnig et al., 1999 [139]	80 prospective patients receiving indomethacin prophylaxis for THR compared with 82 patients without	Indomethacin (Oral 50 mg BD)	(i) No effect on prosthetic loosening after cementless hip arthroplasty
Giannoudis et al., 2000 [140]	Retrospective review of 377 patients treated with IM nail	Ibuprophen and Diclofenac	(i) Increased risk for nonunion in patients receiving NSAIDs
Bhandari et al., 2003 [141]	Retrospective review of 192 tibial shaft fractures	Not specified	(i) Relative risk of 2.02 ($P = 0.035$) for patient who take NSAIDs
Burd et al., 2003 [142]	Retrospective review of 282 with acetabular fractures	Indomethacin	(i) Patients receiving indomethacin had increased risk for developing non-union
Sculean et al., 2003 [143]	Randomized blindfied study on 20 patients with deep intrabony defect	Rofecoxib (25 mg/day for 14 days)	(i) No effect on the healing of intrabony periodontal defects
Bhattacharyya et al., 2005 [144]	Retrospective review of 9995 humeral shaft fractures treated nonoperatively	Not specified	(i) Exposure to nonselective NSAIDs in the period 61–90 days after a humeral shaft fracture was associated with nonunion
Meunier et al., 2009 [145]	Randomized study involving 30 patients undergoing total knee replacement	Celecoxib (200 mg BD)	(i) No differences in prosthesis migration, pain scores, range of motion, and subjective outcome were found after 2 years

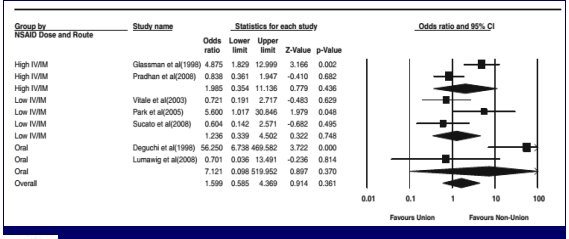
Overall Meta-Analysis



Group by Bone Type	Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Long Bone	Giannoudis et al(2000)	10.741	3.941	29.273	4.641	0.000
Long Bone	Burd et al(2003)	5.622	1.786	17.702	2.951	0.003
Long Bone	Bhandari et al(2003)	2.217	1.050	4.678	2.089	0.037
Long Bone	Bhattacharyya et al(2005)	4.079	2.688	6.191	6.605	0.000
Long Bone		4.408	2.505	7.756	5.146	0.000
Spine	Glassman et al(1998)	4.875	1.829	12.999	3.166	0.002
Spine	Vitale et al(2003)	0.721	0.191	2.717	-0.483	0.629
Spine	Park et al(2005)	5.600	1.017	30.846	1.979	0.048
Spine	Sucato et al(2008)	0.604	0.142	2.571	-0.682	0.495
Spine	Deguchi et al(1998)	56.250	6.738	469.582	3.722	0.000
Spine	Lumawig et al(2008)	0.701	0.036	13.491	-0.236	0.814
Spine	Pradhan et al(2008)	0.838	0.361	1.947	-0.410	0.682
Spine		2.192	0.763	6.304	1.457	0.145
Overall		3.774	2.293	6.211	5.225	0.000

- Dodwell et al Calcif Tissue Int 2010

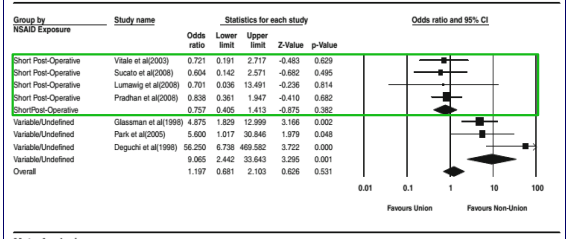
Higher Quality Studies



Group by NSAID Dose and Route	Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
High IV/IM	Glassman et al(1998)	4.875	1.829	12.999	3.166	0.002
High IV/IM	Pradhan et al(2008)	0.838	0.361	1.947	-0.410	0.682
High IV/IM		1.985	0.354	11.136	0.779	0.436
Low IV/IM	Vitale et al(2003)	0.721	0.191	2.717	-0.483	0.629
Low IV/IM	Park et al(2005)	5.600	1.017	30.846	1.979	0.048
Low IV/IM	Sucato et al(2008)	0.604	0.142	2.571	-0.682	0.495
Low IV/IM		1.236	0.339	4.502	0.322	0.748
Oral	Deguchi et al(1998)	56.250	6.738	469.582	3.722	0.000
Oral	Lumawig et al(2008)	0.701	0.036	13.491	-0.236	0.814
Oral		7.121	0.098	519.952	0.897	0.370
Overall		1.599	0.585	4.369	0.914	0.361

- Dodwell et al Calcif Tissue Int 2010

Higher Dose Ketorolac

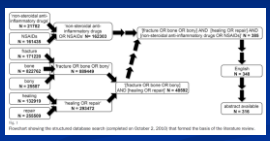


Group by NSAID Exposure	Study name	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value
Short Post-Operative	Vitale et al(2003)	0.721	0.191	2.717	-0.483	0.629
Short Post-Operative	Sucato et al(2008)	0.604	0.142	2.571	-0.682	0.495
Short Post-Operative	Lumawig et al(2008)	0.701	0.036	13.491	-0.236	0.814
Short Post-Operative	Pradhan et al(2008)	0.838	0.361	1.947	-0.410	0.682
Short/Post-Operative		0.757	0.405	1.413	-0.875	0.382
Variable/Undefined	Glassman et al(1998)	4.875	1.829	12.999	3.166	0.002
Variable/Undefined	Park et al(2005)	5.600	1.017	30.846	1.979	0.048
Variable/Undefined	Deguchi et al(1998)	56.250	6.738	469.582	3.722	0.000
Variable/Undefined		9.065	2.442	33.643	3.295	0.001
Overall		1.197	0.681	2.103	0.626	0.531

- Dodwell et al Calcif Tissue Int 2010

Evidence Based Review

- The balance of evidence … appears to suggest that a short-duration NSAID regimen is a safe and effective supplement to other modes of post-fracture pain control, without a significantly increased risk of sequelae related to disrupted healing



The Effect of Nonsteroidal Anti-Inflammatory Drug Administration on Acute Phase Fracture-Healing: A Review

Andrew P. Kurmis, BMBS, PhD, Timothy P. Kurmis, BMBS, Justin X. O'Brien, BMBS, and Tony Dubin, MD, PhD

The Journal of Bone & Joint Surgery · jbjs.org
Volume 94-A · Number 9 · May 2, 2012

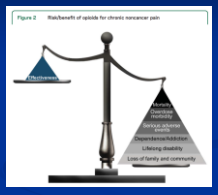
Non-selective NSAIDs

- Less effect on bone healing
  - Selective still helpful with side-effects of NSAIDs

Gerstenfeld LC, Thiede M, Seibert K, Mielke C, Phippard D, Svagr B, Cullinane D, Einhorn TA. Differential inhibition of fracture healing by non-selective and cyclooxygenase-2 selective non-steroidal anti-inflammatory drugs. J Orthop Res. 2003 Jul;21(4):670-5.

Are we OK with Opioid Monotherapy being the standard for musculoskeltal pain?

- Primarily US
- Past 15 to 20 years
- Industry driven
  - Multi-billion dollar industry
  - JCAHO/Joint Commission



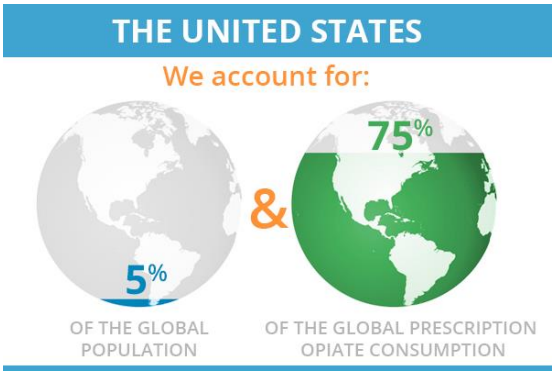
SPECIAL ARTICLE

Opioids for chronic noncancer pain

A position paper of the American Academy of Neurology

Gary M. Franklin, MD, MPH

Neurology® 2014;83:1277-1284



Wake Forest Baptist Medical Center

Fraudulent Marketing: OxyContin

- "with the intent to defraud or mislead," it marketed and promoted OxyContin as a drug that was less addictive, less subject to abuse and less likely to cause other narcotic side effects than other pain medications.

United States Attorney's Office Western District of Virginia [news release]. Available at: http://www.dodig.osd.mil/ IGInformation/IGInformationReleases/ prudue_frederick_1.pdf. Accessed September 11, 2008.

Efficacy no better

Hale ME, Fleischmann R, Salzman R, et al. Efficacy and safety of controlledrelease versus immediate-release oxycodone: randomized, double-blind evaluation in chronic back pain. Clin J Pain. 1999;15:179–183.

Kaplan R, Parris WC, Citron ML, et al. Comparison of controlled-release and immediate-release oxycodone in cancer pain. J Clin Oncol. 1998;16:3230–3237.

Staumbaugh JE, Reder RF, Stambaugh MD, et al. Double-blind, randomized comparison of the analgesic and pharmacokinetic profiles of controlledand immediate-release oral oxycodone in cancer pain patients. J Clin Pharmacol. 2001;41:500–506.

Heiskanen T, Kalso E. Controlled-release oxycodone and morphine in cancer related pain. Pain. 1997;73:37–45.

Mucci-LoRusso P, Berman BS, Silberstein PT, et al. Controlled-release oxycodone compared with controlledrelease morphine in treatment of cancer pain: a randomized, double-blind, parallel-group study. Eur J Pain. 1998; 2:239–249.

Bruera E, Belzile M, Pituskin E, et al. Randomized, double-blind, cross-over trial comparing safety and efficacy of oral controlled-release oxycodone with controlled- release morphine in patients with cancer pain. J Clin Oncol. 1998;16: 3222–3229.

Big business

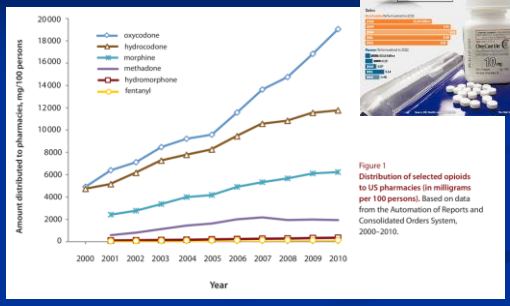


Figure 1
Distribution of selected opioids to US pharmacies (in milligrams per 100 persons). Based on data from the Automation of Reports and Consolidated Orders System, 2000–2010.

Significant payments to pain KOLs, pain societies, and pain advocacy groups


American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics

by Charles Ornstein and Tracy Weber
ProPublica, May 8, 2012, 7:37 p.m.


THE WALL STREET JOURNAL.
A Pain-Drug Champion Has Second Thoughts


Pain experts

- UW Pain & Policy Studies Group
  - $2.5 million paid by opioid manufacturers

http://hcrenewal.blogspot.com/2012/12/the-king-of-pain-recants-pharmaceutical.html
http://www.jsonline.com/watchdog/watchdogreports/119130114.html

Pain Management:
Opioid monotherapy vs. multimodal

- Opioid monotherapy
  - Short acting alone
  - Short and long acting
- Multi-modal
  - Short course, short-acting opioids
  - NSAIDS
  - Gabapentin


Review Article

Approach to Pain Management in Chronic Opioid Users Undergoing Orthopaedic Surgery

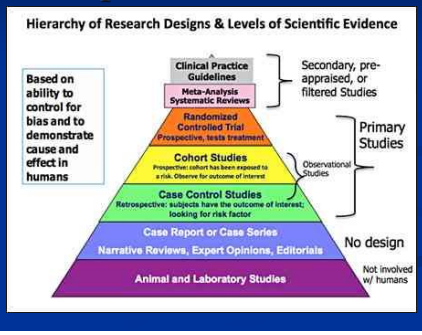
Abstract

Journal of the American Academy of Orthopaedic Surgeons

October 2014, Vol 22, No 10

Show me the data for NCP

What is the evidence behind opioids for NCP?

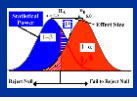


Outcomes Associated with Opioid Use in the Treatment of Chronic Non-Cancer Pain Among Older Adults: A Systematic Review and Meta-Analysis

Maria Papaleontiou, MD[1], Charles R. Henderson Jr.[2], Barbara J. Turner, MD[3], Alison A. Moore, MD, MPH[4], Yelena Olkhovskaya, MD, PhD[5], Leslie Amanfo, BS[5], and M. Carrington Reid, MD, PhD[5]

J Am Geriatr Soc. 2010 July ; 58(7): 1353–1369

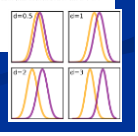
- Moderate improvements pain & physical function vs. placebo
- Comparable to NSAIDs or TCAs
- 30% adverse events
  - Nausea, dizziness
- 25% discontinued



Meta-Analysis of Primary Outcomes

Outcome	Number of studies	No. subjects receiving opioid treatment	No. subjects receiving placebo, wait-list, or non-opioid therapy	Distributional assumption for studies	Placebo mean change[a]	Active mean change[b]	Effect size (active − placebo)[c]	Probability for test of effect size[d]
Pain	10	3,085	1,867	random	−.6045	−1.2340	−.5571	<.0001
Physical Function	9	1,822	903	random	−.3660	−.9977	−.4317	.0015
Quality of Life (PROMIS)	4	972	512	fixed	.4499	.8010	.1911	.1717
Quality of Life (Mental)	4	972	512	fixed	.1844	−.0361	−.2205	.0207
Sleep	6	1,659	825	fixed	.7723	1.4209	.1036	.3492

[a] Least squares means from the model for placebo.
[b] Least squares means from the model for active treatment.
[c] Difference of the 2 least squares means (active − placebo).
[d] Test of the treatment effect.



REVIEW

Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects

CMAJ · MAY 23, 2006 · 174(11)

Andrea D. Furlan, Juan A. Sandoval, Angela Mailis-Gagnon, Eldon Tunks

- Disclaimer: most studies industry funded…
- Only short term studies

Table 1: Types and doses of opioid medications and their associated pain diagnoses.

Medication*	Mean dose (range), mg/d	Type of pain diagnosed; no. of trials (patients)				Total no. of trials (patients)
		Nociceptive	Neuropathic	Mixed	Fibromyalgic	
Codeine	120 (30-180)	4 (292)	1 (3)	–	–	5 (295)
Codeine CR	295.4 (180-400)	2 (149)	–	–	–	2 (149)
Dextropropoxyphene	180	1 (846)	–	–	–	1 (846)
Morphine	NR (20-120)	1 (20)	1 (12)	1 (49)	–	3 (81)
Morphine CR	75.5 (15-240)	1 (295)	3 (114)	–	–	4 (409)
Morphine SR	83.5 (20-300)	1 (61)	–	–	–	1 (61)
Oxycodone IR	40.3 (20-60)	1 (107)	–	–	–	1 (107)
Oxycodone CR	38.5 (10-120)	1 (133)	3 (254)	–	–	4 (387)
Oxycodone + morphine SR†	41.1 (2.9-200)	–	–	1 (23)	–	1 (23)
Propoxyphene	260 –	2 (228)	–	–	–	2 (228)
Tramadol	258 (375-600)	11 (2711)	4 (338)	–	2 (384)	17 (3433)
Totals		25 (4842)	12 (725)	2 (72)	2 (384)	41 (6019)

Note: CR – controlled release, NR – not reported, SR – sustained release, IR – immediate release.
*Oxycodone and morphine were categorized as strong opioids; the others, as weak opioids.
†Morphine-equivalent doses.

Table 2: Duration of opioid therapy

Diagnosis	No. of studies	Duration of therapy (wk)		
		Average	Minimum	Maximum
Nociceptive pain	25	4.8	1	13
Neuropathic pain	12	4.4	1	6
Mixed pain	2	8.5	1	16
Fibromyalgia	2	8.8	6	11.5
Total	41	5.0	1	13

Only 2 studies up to 16 weeks

REVIEW

Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects

CMAJ · MAY 23, 2006 · 174(11)

Andrea D. Furlan, Juan A. Sandoval, Angela Mailis-Gagnon, Eldon Tunks

- Disclaimer: most studies industry funded…
- Only short term studies
- No difference funtional outcome

- Opioids were effective in the treatment of CNCP overall: they reduced pain and improved functional outcomes better than placebo.
- Opioids were more effective than placebo for both nociceptive and neuropathic pain syndromes.
- Tramadol reduced pain and improved functional outcomes in patients with fibromyalgia.
- Strong opioids (oxycodone and morphine) were significantly superior, statistically, to naproxen and nortriptyline (respectively) for pain relief but not for functional outcomes.
- Weak opioids (propoxyphene, tramadol and codeine) did not significantly outperform NSAIDs or TCAs for either pain relief or functional outcomes.
- Clinically (> 10%) and statistically, only constipation and nausea were significantly more common with opioids.

What about Chronic Non Cancer Pain (CNCP)?

- persons in chronic pain on opioids reported decreased pain relief, functional capacity, and quality of life vs persons in chronic pain not on opioids, adjusting for severity
- Opposite marketing claims

Eriksen J, Sjogren P, Bruera E, Ekholm O, Rasmussen NK. Critical issues on opioids in chronic non-cancer pain: an epidemiological study. Pain 2006;125:172–179

Are higher doses better?

- Liberally escalating dosage vs. "hold the line" dosage
  - No significant improvement primary pain and functional outcome escalating
  - 27% overall discharged from trial (misuse/noncompliance)

VA U.S. Department of Veterans Affairs

Naliboff BD, Wu SM, Schieffer B, et al. A randomized trial of 2 prescription strategies for opioid treatment of chronic nonmalignant pain. J Pain 2011;12:288–296.

Higher Opioid Doses Predict Poorer Functional Outcome in Patients with Chronic Disabling Occupational Musculoskeletal Disorders

By Cindy L. Kidner, PhD, Tom G. Mayer, MD, and Robert J. Gatchel, PhD, ABPP

Investigation performed at PRIDE Research Foundation, Dallas, Texas

J Bone Joint Surg Am. 2009;91:919-27

- Functional rehab
  - Yes – taking opioids
  - No – not taking
- Work return and retention inverse to dose

TABLE V One-Year Post-Rehabilitation Socioeconomic Outcomes: Opioid Subgroups Controlled for Pre-Rehabilitation Length of Disability (Completers Only)

Variable	No	Low	Medium	High	Very High	P Value*	R^2
Number of patients (% of total) (n = 887)	513 (57.8)	205 (23.1)	75 (8.5)	53 (6.0)	41 (4.6)		
Work return (%)	93.7	88.7	89.5	90.7	75.9	0.05	0.107
Work retention (%)	85.2	70.1	63.0	69.0	55.2	<0.001	0.132
Surgery to same body part (%)	2.1	5.5	2.1	7.7	7.4	NS	
Seeking treatment from new provider (%)	14.0	28.8	36.7	28.2	29.6	0.001	0.052
New injury to same body part (%)	4.4	3.8	13.0	6.3	4.2	NS	
Workers' Compensation case settlement (%)	97.2	98.6	98.0	95.0	100.0	NS	
SSDI or SSI† (%)	1.9	5.7	3.9	4.5	18.5	0.03	0.176

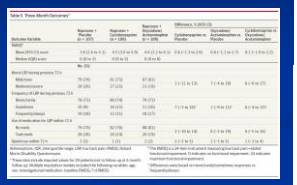
*NS = not significant. †SSDI = Social Security Disability Income, SSI = Supplemental Security Income.

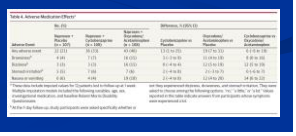
Naproxen With Cyclobenzaprine, Oxycodone/Acetaminophen, or Placebo for Treating Acute Low Back Pain
A Randomized Clinical Trial

Benjamin W. Friedman, MD, MS; Andrew A. Dym, BS; Michelle Davitt, MD; Lynne Holden, MD; Clemencia Solorzano, PharmD; David Esses, MD; Polly E. Bijur, PhD; E. John Gallagher, MD

JAMA October 20, 2015 Volume 314, Number 15

- All 20 tablets of naproxen 500mg BID
- Randomized (PRN LBP)
  - Placebo
  - Cyclobenzaprine 5mg
  - Oxycodone 5/325
- No difference pain improvement 1 week or 3mos
  - More adverse events





Surgery always needs opioids, right?

Differences in Prescription of Narcotic Pain Medication After Operative Treatment of Hip and Ankle Fractures in the United States and the Netherlands

Anneluuk L. C. Lindenhovius, MSc, Gijs T. T. Helmerhorts, MSc, Alexandra C. Schnellen, MSc, Mark Vrahas, MD, David Ring, MD, and Peter Kloen, MD, PhD

The Journal of **TRAUMA®** *Injury, Infection, and Critical Care* • Volume 67, Number 1, July 2009

TABLE 3. Comparison of Narcotics Prescription Between Countries

	American	Dutch	*p*
Hip fractures			
Inpatient	85	58	<0.001
Outpatient	77	0	<0.001
Ankle fractures			
Inpatient	98	64	<0.001
Outpatient	82	6	<0.001

Patient satisfaction: Cultural?

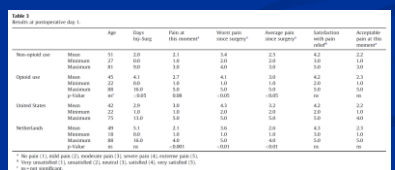
Satisfaction with pain relief after operative treatment of an ankle fracture

Gijs T.T. Helmerhorst [a,e], Anneluuk L.C. Lindenhovius [b,e], Mark Vrahas [c], David Ring [d,*], Peter Kloen [a]

[a] *Department of Orthopaedic Surgery, Academic Medical Center, University of Amsterdam, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands*
[b] *Resident in Orthopaedic Surgery, Academic Medical Center, University of Amsterdam, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands*
[c] *Orthopaedic Trauma Service, Orthopaedic Hand and Upper Extremity Service, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, USA*
[d] *Orthopaedic Hand and Upper Extremity Service, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, USA*

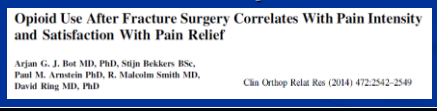
Injury, Int. J. Care Injured 43 (2012) 1958–1961

- Prospective, observational
- USA vs. Netherlands
  - Very few opioids in Netherlands



What about Satisfaction Scores?

- Higher opioid doses post-op
  - Greater reported pain
  - Decreased satisfaction with pain relief



Opioid Use After Fracture Surgery Correlates With Pain Intensity and Satisfaction With Pain Relief

Arjan G. J. Bot MD, PhD, Stijn Bekkers BSc, Paul M. Arnstein PhD, R. Malcolm Smith MD, David Ring MD, PhD

Clin Orthop Relat Res (2014) 472:2542–2549

Chen L, Vo T, Seefeld L, Malarick C, Houghton M, Ahmed S, Zhang Y, Cohen A, Retamozo C, St Hilaire K, Zhang V, Mao J. Lack of correlation between opioid dose adjustment and pain score change in a group of chronic pain patients. J Pain. 2013; 14:384–392.

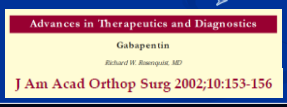
Trevino CM, deRoon-Cassini T, Brasel K. Does opiate use in traumatically injured individuals worsen pain and psychological outcomes? J Pain. 2013;14:424–430.

Other agents

Gabapentin

- Neuropathic component
- Complex pain management
  - Previous opioid use
  - High dose requirements

Similar effect pregabalin



Advances in Therapeutics and Diagnostics

Gabapentin

Richard W. Rosenquist, MD

J Am Acad Orthop Surg 2002;10:153-156

Ho KY, Gan TJ, Habib AS. Gabapentin and postoperative pain--a systematic review of randomized controlled trials. Pain. 2006 Dec 15;126(1-3):91-101.

Gabapentin

- CRPS

Mellick GA, Mellicy LB, Mellick LB: Letter: Gabapentin in the management of reflex sympathetic dystrophy. J Pain Symptom Manage 1995;10:265-266.

- Long term doses up to 2400mg/day
- Short term doses up to 3600mg/day
- Acute pain

Werner MU, Perkins FM, Holte K, Pedersen JL, Kehlet H: Effects of gabapentin in acute inflammatory pain in humans. Reg Anesth Pain Med 2001;26:322-328.

- Neuropathic pain

Moore RA, Wiffen PJ, Derry S, Toelle T, Rice AS. Gabapentin for chronic neuropathic pain and fibromyalgia in adults. Cochrane Database Syst Rev. 2014 Apr 27;4:CD007938.

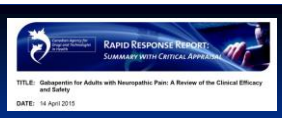


Table 2: Assessment of substantial benefit (defined as at least 50% pain intensity reduction) with gabapentin compared to placebo

Condition	No. of RCTs	No. of patients	Patients with substantial benefit (%) G vs plb	RR (95% CI)	NNT (95% CI)
PHN	6	1816	34 vs 21	1.6 (1.3 to 1.9)	8.0 (6.0 to 12)
DPN	6	1277	38 vs 21	1.9 (1.5 to 2.3)	5.9 (4.6 to 8.3)
Mixed NP	1	305	21 vs 14	1.5 (0.9 to 2.4)	NC
NIP	1	98	13 vs 9	1.4 (0.7 to 3.2)	NC
Small fibre sensory neuropathy	1	18	22 vs 6	5 (0.65 to 38.65)	NC

CI = confidence interval, DPN = diabetic peripheral neuropathy, G = gabapentin, NC = not calculated, NIP = nerve injury pain, NNT = number needed to treat to benefit, NP = neuropathic pain, PHN = postherpetic neuralgia, plb = placebo, RCT = randomized controlled trial, RR = risk ratio, vs = versus

Gabapentin for Adults with Neuropathic Pain: A Review of the Clinical Efficacy and Safety [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2015 Apr 14.

NSAIDs Clinical Scenarios

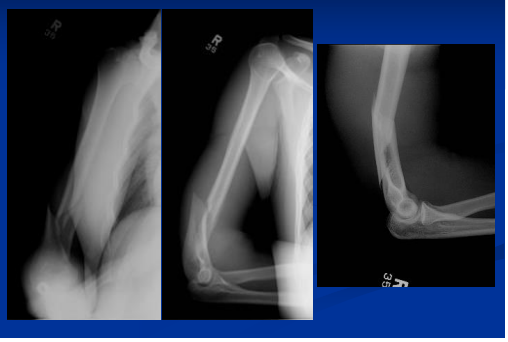
- Contraindications
  - Renal insufficiency
  - Allergy
  - Peptic Ulcer Disease

Clinical Scenarios

- ED management
- Non-operative
- Operative
  - Peri-operative
  - Outpatient
- Special cases
  - Nonunion
  - Osteotomy
  - Bone transport

Emergency Department

26 y.o. male



Cost effective?

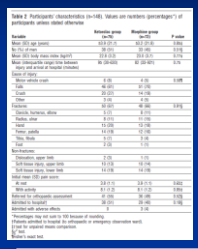


Table 3 Participants' satisfaction with analgesia and with emergency department management

Variable	Median (interquartile range)		Median difference (95% confidence interval)	P value*
	Ketorolac group	Morphine group		
Satisfaction with analgesia	8.0 (6.0-8.0)	6.0 (4.0-8.0)	1.0 (1.0-2.0)	<0.0001
Satisfaction with emergency department management	8.0 (6.0-8.0)	8.0 (6.0-8.0)	0	0.30

*Mann-Whitney U test.

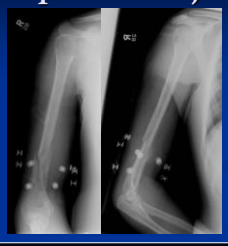
Table 5 Numbers (percentages) of participants with adverse events*

Variable	Ketorolac group (n=75)	Morphine group (n=73)	P value†
Total‡	4 (5)	65 (89)	<0.0001
Drowsiness	1 (1)	43 (59)	<0.0001
Sleeping	0	8 (11)	0.0054
Dizziness	2 (2)	55 (75)	<0.0001
Nausea	0	27 (37)	<0.0001
Vomiting	0	12 (16)	<0.001
Pruritis	0	20 (27)	<0.0001

*Some participants reported more than one adverse effect.
†Fisher's exact test.
‡Includes participants with uncommon adverse effects that are noted in the text but not in the table.

Rainer TH, Jacobs P, Ng YC, Cheung NK, Tam M, Lam PK, Wong R, Cocks RA. Cost effectiveness analysis of intravenous ketorolac and morphine for treating pain after limb injury: double blind randomised controlled trial. BMJ. 2000 Nov 18;321(7271):1247-51.

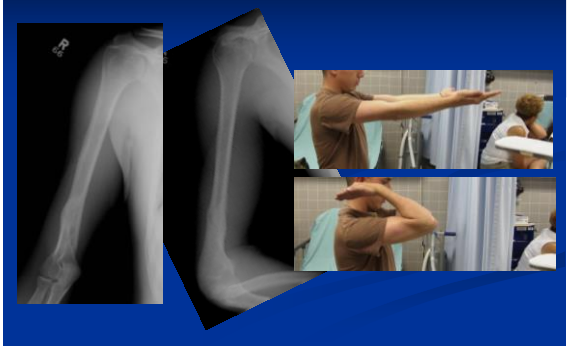
Non-operative injuries



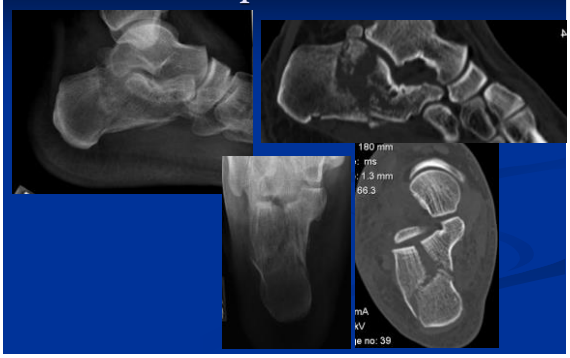
Craig M, Jeavons R, Probert J, Benger J. Randomised comparison of intravenous paracetamol and intravenous morphine for acute traumatic limb pain in the emergency department. Emerg Med J. 2012 Jan;29(1):37-9.

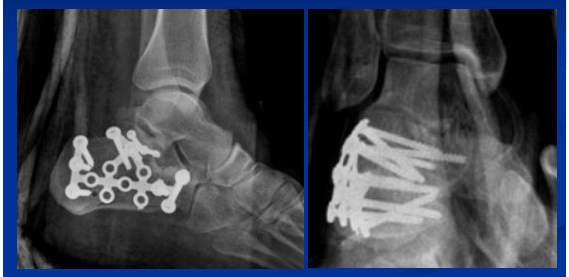
Davis TRC, Ackroyd CE. Non-steroidal anti-inflammatories in the treatment of Colles' fractures. Br J Clin Pract 1988;42(5):184-9.

Healed, good function, pain free



Operative





NSAIDs work after surgery

Kang H, Ha YC, Kim JY, Woo YC, Lee JS, Jang EC. Effectiveness of multimodal pain management after bipolar hemiarthroplasty for hip fracture: a randomized, controlled study. J Bone Joint Surg Am. 2013 Feb 20;95(4):291-6.

Maheshwari AV, Boutary M, Yun AG, Sirianni LE, Dorr LD. Multimodal analgesia without routine parenteral narcotics for total hip arthroplasty. Clin Orthop Relat Res. 2006 Dec;453:231-8.

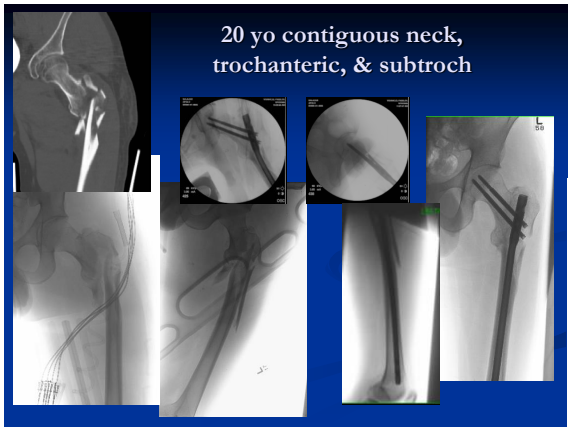
Norman PH, Daley MD, Lindsey RW. Preemptive analgesic effects of ketorolac in ankle fracture surgery. Anesthesiology. 2001 Apr;94(4):599-603.

Derry CJ, Derry S, Moore RA, McQuay HJ. Single dose oral ibuprofen for acute postoperative pain in adults. Cochrane Database Syst Rev 2009;(3):CD001548.

Ketorolac (Toradol)

- IV Ketorolac trometamol: as effective as morphine for surgical pain and pain related to cancer, and it has fewer side effects.
- Gillis JC, Brogden RN. Ketorolac. A reappraisal of its pharmacodynamic and pharmacokinetic properties and therapeutic use in pain manage ment. Drugs 1997;53:13988.
- GI haemorrhage risk only slightly higher with ketorolac than morphine (odds ratio 1.17 (95% CIs 0.991.13)); risk rises sharply more than five days or in patients older than 75

Strom BL, Berlin JA, Kinman JL, Spitz PW, Hennessy S, Feldman H, et al. Parenteral ketorolac and risk of gastrointestinal and operative site bleed ing. A postmarketing surveillance study. JAMA 1996;275:37682.



Operative injuries

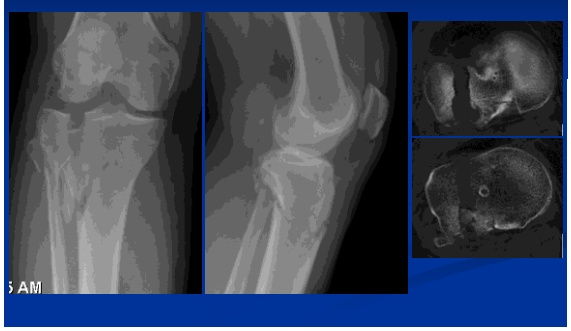
- Cultural expectations
- Equivalent or better outcomes NSAIDs
  - Hip, ankle, and femur fractures

Lindenhovius AL, Helmerhorst GT, Schnellen AC, Vrahas M, Ring D, Kloen P. Differences in prescription of narcotic pain medication after operative treatment of hip and ankle fractures in the United States and The Netherlands. J Trauma. 2009 Jul;67(1):160-4.

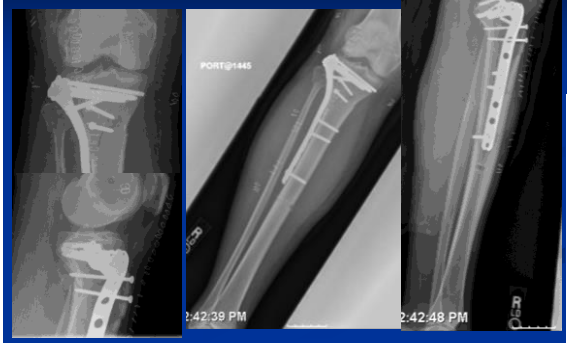
Helmerhorst GT, Lindenhovius AL, VrahasM, Ring D, Kloen P. Satisfaction with pain relief after operative treatment of an ankle fracture. Injury. 2012 Nov;43(11):1958-61.

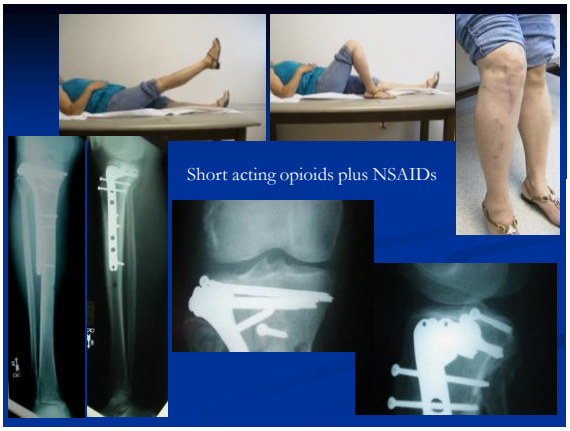
Carragee EJ, Vittum D, Truong TP, Burton D. Pain control and cultural norms and expectations after closed femoral shaft fractures. Am J Orthop (Belle Mead NJ). 1999;28:97–102.

Peri-operative

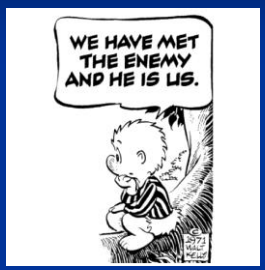


Ketorolac





Own our influence on pain management

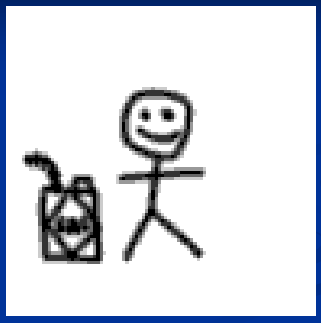


- Walter Crawford Kelly, Jr. (August 25, 1913 – October 18, 1973)

50% of patients taking opioids for at least 3 months are still on opioids 5 years later

Martin BC, Fan MY, Edlund MJ, Devries A, Braden JB, Sullivan MD. Long-term chronic opioid therapy discontinuation rates from the TROUP study. J Gen Intern Med 2011;26:1450–1457.

Instead of this reaction to NSAIDS…



Weigh the facts

- NSAIDs and delayed bone healing
  - Clinical Association ≠ causation
  - Conflicting basic science
- Opioids and delayed bone healing
  - Clinical Association ≠ causation
  - Some evidence in basic science
- Opioids and dependence
  - Causation clear
- Opioids and death
  - Causation clear

What are we doing about it?

Prescription Reporting with Immediate Medication Utilization Mapping (PRIMUM)

Principal Investigators: Rachel Seymour, PhD, and Joseph Hsu, MD

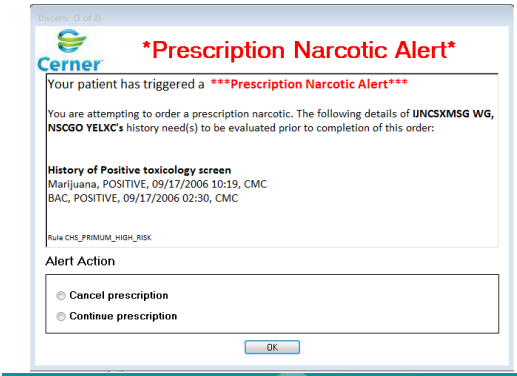
Co-investigators: Michael Beuhler, MD; Michael Bosse, MD; Stephen Colucciello, MD; Michael Gibbs, MD; Steven Jarrett, PharmD; Michael Runyon, MD; Animita Saha, MD; Brad Watling, MD; Christopher Griggs, MD; Stephen Wyatt, DO; Daniel Leas, MD; Sharon Schiro, PhD; Meghan Wally, MSPH

- Goals:

1) To identify patients at high risk for misuse, abuse, and diversion of prescription opioids and benzodiazepines.
2) To provide critical information to the prescriber at the point of care in order to inform clinical decision-making

Intervention: Alert System

- Prescriber selects controlled substance
- EMR searches patient chart for defined risk factors for abuse/misuse/diversion
- Provides prescriber with alert
- Prescriber can continue or discontinue script.



What can be done?

- Become conversant in the problem
- Stop prescribing long acting
- Multi-modal pain management
- Local policy
- Utilize PDMP or implement decision support

Useful Tools and Tips on Opioids

- Difficult discussion
- Frame as patient safety
- Enroll reasonable family member
  - If available
- Consistent policies and procedures
  - Blame the policy

Assess sedation: Pasero scale

Pasero Opioid-induced Sedation Scale (POSS)

S = Sleep, easy to arouse
Acceptable; no action necessary; may increase opioid dose if needed

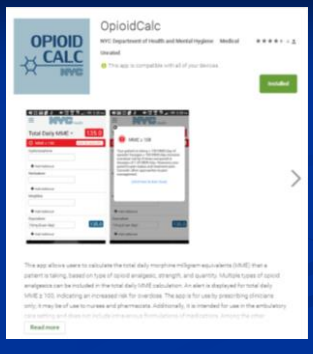
1. Awake and alert
Acceptable; no action necessary; may increase opioid dose if needed

2. Slightly drowsy, easily aroused
Acceptable; no action necessary; may increase opioid dose if needed

3. Frequently drowsy, arousable, drifts off to sleep during conversation
Unacceptable; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory; decrease opioid dose 25% to 50% or notify prescriber or anesthesiologist for orders; consider administering a non-sedating, opioid-sparing nonopioid, such as acetaminophen or an NSAID, if not contraindicated.

4. Somnolent, minimal or no response to verbal or physical stimulation
Unacceptable; stop opioid; consider administering naloxone; notify prescriber or anesthesiologist; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory.

Assess risk with MME Calculator



CDC Guidelines

- 12 guidelines, 56 pages
- chronic pain (i.e., pain lasting >3 months or past the time of normal tissue healing)

http://www.cdc.gov/drugoverdose/prescribing/guideline.html

New trend?
Blame the courts

"Low T"

- Healing, bone mineral density, erectile dysfunction, libido, etc.

Evaluating the Affect and Reversibility of Opioid-induced Androgen Deficiency in an Orthopaedic Animal Fracture Model

Jesse Chrastil MD, Christopher Sampson BS, Kevin B. Jones MD, Thomas F. Higgins MD

Clin Orthop Relat Res (2014) 472:1964–1971

De Maddalena C, Bellini M, Berra M, Meriggiola MC, Aloisi AM. Opioid-induced hypogonadism: why and how to treat it. Pain Physician. 2012 Jul;15(3 Suppl):ES111-8.

Aloisi AM, Ceccarelli I, Carlucci M, Suman A, Sindaco G, Mameli S, Paci V, Ravaioli L, Passavanti G, Bachiocco V, Pari G. Hormone replacement therapy in morphine-induced hypogonadic male chronic pain patients. Reprod Biol Endocrinol. 2011 Feb 18;9:26.

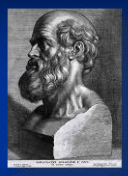
Birthi P, Nagar VR, Nickerson R, Sloan PA. Hypogonadism associated with long-term opioid therapy: A systematic review. J Opioid Manag. 2015 May-Jun;11(3):255-78.

Rubinstein A, Carpenter DM. Elucidating risk factors for androgen deficiency associated with daily opioid use. Am J Med. 2014 Dec;127(12):1195-201. doi: 10.1016/j.amjmed.2014.07.015. Epub 2014 Jul 22.

Demarest SP, Gill RS, Adler RA. Opioid endocrinopathy. Endocr Pract. 2015 Feb 1;21(2):190-8.

Multi-modal strategy

- Short acting opioids
  - 8 weeks maximum
    - Refer to pain management if requiring more narcotics
- NSAIDs
  - Non-selective:
    - Ibuprofen, naproxen, etc.
  - Selective if GI risk:
    - Meloxicam (generic)
- Gabapentin
  - Up to 1800 mg/day effective
  - Increased evening dose



"Primum non nocere"

- No sustained-release opioids
- No sedative-hypnotics
  - Benzos, ambien, etc.

Thank you

Discussion