Multi-modal Pain Management in Foot and Ankle Surgery

Craig S. Radnay, MD, MPH

ISK Institute for Orthopaedics and Sports Medicine
NYU/Hospital for Joint Diseases

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Peri-operative Goals in Foot and Ankle Surgery

- Minimize pain
- Minimize complications
- Maximize early and late recovery

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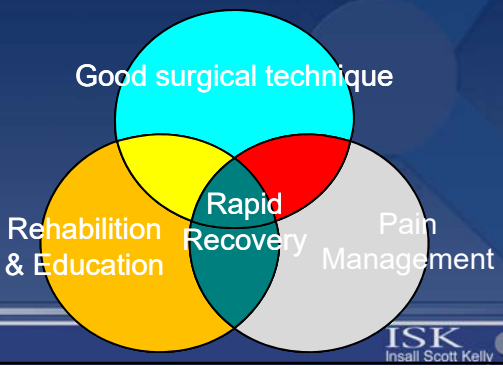
Keys to a Successful Surgery



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Mechanism of Surgical Pain

- Surgery activates the nociceptor system[1,2]
  - Central nervous system (CNS)
  - Peripheral nervous system
    - A delta (Aδ) fibers
      - Myelinated
      - Rapid transmission to CNS
      - Mechanical and thermal stimuli
    - C fibers
      - Unmyelinated
      - Mechanical, chemical, cold stimuli
      - Involved in inflammation

1. Peripheral tissues

2. Spinal cord

3. Brain

1. Dalury DF, et al. J Bone Joint Surg Am. 2011;93:1938-1943.
2. Vanderah TW. Med Clin N Amer. 2007;91:1-12.

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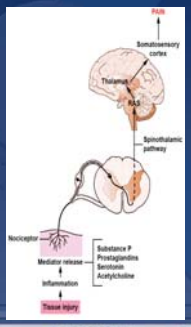
Mechanism of Surgical Pain

- Secondary inflammation
- Tissue damage
  - Inflammatory mediators/cytokines
- Reduction in pain threshold of nociceptor afferent nerves
- Hyperalgesia
  - Primary – injured tissue
  - Secondary – noninjured tissue
- Sensitization
  - Peripheral – inflammation
  - Central – repeated stimuli



Dalury DF, et al. J Bone Joint Surg Am. 2011;93:1938-1943

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Background

- More than 90 million procedures performed in the U.S. each year[1,2]
- 35 million ambulatory
- 56 million in-patient[1,2]
  - Orthopedic patients had the highest incidence of pain compared to other types of operations
  - >50% experience suboptimal pain control

1 Cullen KA, et al. Natl Health StatReport. 2009; 28 (11): 1-25. 2 Apfelbaum JL, et al. Anesth Analg. 2003; 97 (2): 534-540. 3 Centers for Disease Control and Prevention. FastStats. 2009. 4 Parvataneni HK, et al. J Arthroplasty. 2007; 22 (6) (suppl 2): 33-37. 5. Chung et al. Anesth Analg 1997

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Pain Management

Physicians[1,2]

- *Perioperative "hassle"*
- *Impaired rehabilitation*
- *Compromised outcomes*
- *Chronic pain*
- *Complications*

Patients[1,2]

- *Fear*
- *Dissatisfaction*
- *Complex physiology*
- *Increased morbidity*
- *Hindered physiotherapy*
- *Increased anxiety*
- *Disrupted sleep*
- *Prolonged recovery*

LOS – length of hospital stay

1. Barrington JW, et al. *Am J Orthop.* 2014;43(4 Suppl):S1-S16.
2. Dulany DF, et al. *J Bone Joint Surg Am.* 2011;93(20):1938-1943.

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Pain Management

Hospitals[1,2]

- *"5th vital sign"*
- *Prolonged LOS*
- *Quality measure*
- ***Joint Commission:*** *"…patients have a right to adequate pain management"[1]*

Health Economics[1,2]

- *Prolonged LOS*
- *Prolonged recovery*
- *Disability*
- *Medication side effects*

LOS – length of hospital stay

1. Dulany DF, et al. *J Bone Joint Surg Am.* 2011;93(20):1938-1943.
2. Barrington JW, et al. *Am J Orthop.* 2014;43(4 Suppl):S1-S16.
3. Peake IL. 44 hospitals great at pain management. *Infection Control & Clinical Quality.* December 4, 2014. http://www.beckershospitalreview.com/quality/44-hospitals-great-at-pain-management.html. Accessed October 27, 2014.

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How To Improve Our Outcomes Following Surgery?

- Patient expectations
  - Age, motion, activity
- Management of these expectations
  - Pre-operative
  - Peri-operative
  - Post-operative
- Multimodal pain control
- Rapid recovery, rehabilitation

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Develop A Team & A Pathway

- Everyone on same page
  - Physician extenders, Office, Hospital, Home
- Be a "coach" to the patient
  - Instill confidence
- Explain upcoming experience
  - Expectation of pain in preoperative setting is related to amount of pain postoperatively

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Remember: Postoperative Pain is #1 Patient concern

- Orthopedic procedures are among the most painful
- Up to 20% of pts can have pain at 1 yr
- Pain is the most common reason for fear/avoidance of surgery

Mannion et al, Arth Res Ther, 2009; Pour et al, JBJS 2007; Nuelle et al, J Arth 2007; Wu et al, Curr Op Anest 2004; Trousdale et al, Mayo Proc, 1999

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↑Post-Op Pain = ↑Complications

- Prolonged hospital/rehab stay
  - (*Kessler, et al, Morrison, et al*)
- Elevated readmission rate
  - (*Coley, et al*)
- Higher Costs
  - (*Oderda, Pogatzki-Zahn, et al*)
- Postop pain control and rapid rehab protocols correlate with quality of recovery

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Pain Management (2000s)

- Opioid analgesics were the cornerstone of post-operative analgesia following orthopedic surgery
  - Intra-op narcotics
  - IV narcotics
  - IM narcotics
  - PCA pumps
  - Oral long- and short-acting narcotics

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Opioids Were The Conventional Approach

- Opioids (PO or PCA/IV) as the sole source of analgesia are associated with significant issues[1]
- Opioid-related adverse events occur more frequently with[1]
  - Increased age
  - Obesity
  - Chronic COPD
  - Hepatic and/or renal impairment

Opioid-Related Adverse Effects[2]

- Allergy
- Arrhythmias
- CNS adverse events
- Constipation
- Cough
- Dry mouth
- Endocrinopathy
- Histamine release
- Ileus
- Immunomodulation
- Increased intracranial pressure
- Myoclonus
- Nausea and vomiting
- Neurotoxicity
- Pruritus
- Respiratory depression
- Rigidity
- Serotonin syndrome
- Urinary retention
- Withdrawal symptoms

PCA = patient-controlled analgesia; PO = oral; THA = total hip arthroplasty; TKA = total knee arthroplasty.

1. Barrington JW, et al. Am J Orthop. 2014;43(4 Suppl):S3-S16.
2. Ersted BL, et al. Chest. 2009;135(4):1075-1086.

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Effect of Opioid-related Adverse Events on Outcomes

- 319,898 surgeries
- 12.2% patients experienced ORAE
  - Patients had higher adjusted mean costs
    - $22,077 vs $17,370 (p <0.0001)
  - Greater LOS
    - 7.6 vs 4.2 days (p <0.0001)
  - More likely to be readmitted (OR 1.06)

ORAE=opioid-related adverse events.

Oderda GM, et al. J Pain Palliative Care Pharmacother. 2013.

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Opioid Epidemic

U.S.

Rising rates of hepatitis C and HIV in rural America, including in small cities like Portsmouth, Ohio, and Austin, Ind., have reignited the debate about needle-exchange programs. Photo: Josh Birnbaum for The Wall Street Journal

Rural U.S. Struggles to Combat IV Drug Abuse

Hepatitis C and HIV outbreaks test public-health resources in Midwestern states

By JEANNE WHALEN in Portsmouth, Ohio, and ARIAN CAMPO-FLORES in Austin, Ind.

Abuse of opioid painkillers and heroin in rural areas and small cities is causing hepatitis C and HIV to spread in regions where they were uncommon two decades ago. New hepatitis C infections nationwide rose 150% between 2010 and 2013, with the largest increases in rural areas, according to the Centers for Disease Control and Prevention. Last month, the CDC said new hepatitis C infections in young adults more than quadrupled in four states—Kentucky, Tennessee, Virginia and West Virginia—from 2006 to 2012, with many cases linked to injection-drug use. Infections in Ohio have grown by 50% over the past five years.

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Opioid Epidemic

White House Summit on the Opioid Epidemic[1]

"The abuse of opioids…has a devastating impact on public health and safety in this country[1]"

46
Each day, 46 people die from an overdose of prescription painkillers* in the US[2]

259 M
HCPs wrote 259 million prescriptions for painkillers in 2012, enough for every American adult to have a bottle of pills[2]

10
10 of the highest prescribing states for painkillers are in the South[2]

**Opioid or narcotic pain relievers, including drugs such as hydrocodone bitartrate and acetaminophen tablets, oxycodone, oxymorphone, and methadone.*
1. Office of National Drug Control Policy. http://www.whitehouse.gov. 2. CDC Vital Signs. http://www.cdc.gov.

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Hospitalizations and Emergency Department Visits Due to Opioid Overuse/Misuse Continue to Rise

- Between 2002 and 2012, hospitalization rates for opioid overuse among adults ≥18 years increased by >60%, with 709,500 opioid-related hospitalizations in 2012[1]
  - The highest rate is currently in individuals aged 45–64 years
- Between 2006 and 2010, emergency department visits involving non-medical use of POs increased 112% (from 84,671 to 179,787)[2]

Overall Hospitalization Rates

Hospitalization Rates by Age Group

1. Kronick R. AHRQ Data Reveal Wider Impact of Opioid Overuse. http://www.ahrq.gov. 2. US Department of Justice, Drug Enforcement Administration. National Drug Threat Assessment Summary 2013. http://www.dea.gov.

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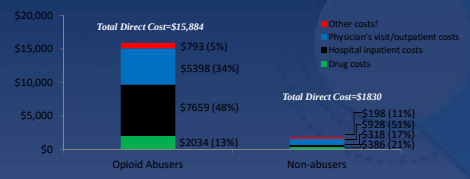
Opioid Abuse Results in High Healthcare Costs

Average Annual Direct Costs of Opioid Abusers and Non-abusers, 1998–2002*



- Administrative database of medical and pharmacy claims from 1998–2002
- Patients with claims associated with codes for opioid abuse were identified; a control group of non-abusers was selected using a matched sample in a 3:1 ratio

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Recent Gains in Knowledge: Multimodal Pain Management

- Minimize use of narcotics
  - Eliminate parenteral narcotics
- Decrease pain scores
- Decrease adverse side effects
- Increase patient satisfaction
- Decrease times to reach PT milestones

- Surgeon, pain management team compliance
- Well tolerated by patients

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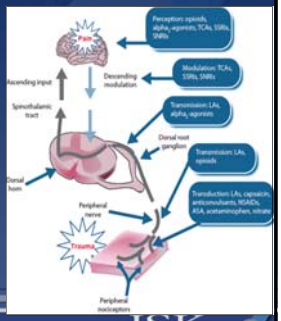
Effective Pain Control Requires a Combined Drug Synergy Effect

- Block generation and perception of pain at *several different* stages in pathway
- Stop pain before it starts
  - Neuraxial/Regional anesth
- Multimodal analgesia
  - Potentiate effect of each 1 treatment individually



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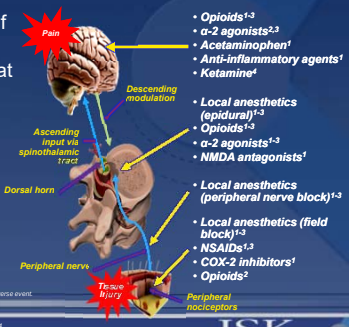
A Multimodal Approach Uses a Variety of Therapeutics That Work at Different Sites

- Simultaneous use of a combination of ≥2 analgesics that act at different sites within the central and peripheral nervous systems in an effort to[1,2]:
  - Reduce pain
  - Minimize opioid use and ORAEs



- Opioids[1-3]
- α-2 agonists[2,3]
- Acetaminophen[1]
- Anti-inflammatory agents[1]
- Ketamine[4]
- Local anesthetics (epidural)[1-3]
- Opioids[1-3]
- α-2 agonists[1-3]
- NMDA antagonists[1]
- Local anesthetics (peripheral nerve block)[1-3]
- Local anesthetics (field block)[1-3]
- NSAIDs[1,3]
- COX-2 inhibitors[1]
- Opioids[2]

COX = cyclooxygenase; NMDA = N-methyl-D-aspartate; NSAID = nonsteroidal anti-inflammatory drug; ORAE = opioid-related adverse event.

1. Gandhi K, Viscusi E. J NYSORA. 2009;13:1-10.
2. Kehlet H, Dahl JB. Anesth Analg. 1993;77(5):1048-1056.
3. Gottschalk A, Smith DS. Am Fam Physician. 2001;63(10):1979-1984.
4. Yu H, et al. Neurotoxicology. 2012;33(1):70-77.

Figure adapted with permission from: Kehlet H, Dahl JB. Anesth Analg. 1993;77(5):1048-1056.

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A Multimodal Approach Is Recommended From Preoperative Stage to Discharge

PREOPERATIVE (Preemptive)[1-6]
- NSAIDs/COX-2
- Long-acting narcotic
- Acetaminophen
- Dexamethasone

INTRAOPERATIVE (Preemptive and Multimodal)[2,5-8]
- Regional anesthesia
- Peripheral nerve blocks
- Periarticular injections

POSTOPERATIVE (*on schedule*) (Multimodal)[2,3,5,6,8]
- Acetaminophen
- NSAID (COX-2)
- Narcotic (ATC vs breakthrough PRN)

DISCHARGE[2,5,6]
- Acetaminophen
- NSAIDs (COX-2)
- Narcotic
- Combinations

ATC = around-the-clock; COX-2 = cyclooxygenase-2; NSAID = nonsteroidal anti-inflammatory drug; PRN = taken as needed.

2. Gandhi K, Viscusi E. J NYSORA. 2009;13:1-10.
3. Kehlet H, Dahl JB. Anesth Neurotoxicology. 2012;33(1):70-77.
4. Waldron NH, et al. Br J Anaesth. 2013;1(2):191-200.
6. Halawi MJ, et al. Orthopedics. 2015;38(7):e618-e625.
7. Barrington JW, et al. Am J Orthop. 2014;43(4Suppl):S1-S16.
8. American Society of Anesthesiologists Task Force on Acute Pain Management. Anesthesiology. 2012;116(2):248-273

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Preoperative Medications: Prevent/Minimize Initiation of Pain

- Oxycontin
  - Acts in dorsal ganglia and centrally
  - 10mg am pre-op

Meunier et al., Acta Orthop 2009, 2007; Reuben et al., Anesth Analg 2008; O'Connor & Lysz, Drugs Today (Barc) 2008; Huang et al., BMC Musculoskelet Disord 2008

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Preoperative Medications: Prevent/Minimize Initiation of Pain

- Acetaminophen
  - 1000mg am pre-op
  - Central inhibitory effect
  - 1g PO/IV upon induction
  - 1g 4 hrs post-op

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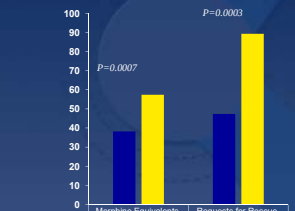
Acetaminophen
Mechanism and Efficacy in Multimodal Therapy

- Acts as a central analgesic[1]
- ASA guidelines suggest around-the-clock acetaminophen be considered part of multimodal pain management[2]
- Reduced use of opioids and requests for rescue medication over the first 24 hours post operation[3]



	Morphine Equivalents, mean, mg	Requests for Rescue Medication, mean, n
IV Acetaminophen	38.3	47.4
Placebo	57.4	89.3

ASA = American Society of Anesthesiologists; IV = intravenous; RCT = randomized, controlled trial

1. Parvizi J, et al. J Bone Joint Surg Am. 2011;93:1075-1084.
2. American Society of Anesthesiologists Task Force on Acute Pain Management. Anesthesiology. 2012;116(2):248-273
3. Sinatra RS, et al. Pain Practice. 2012;12(5):357-365.

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Preoperative Medications: Prevent/Minimize Initiation of Pain

- Celebrex 200/400 mg x 1 am pre-op
  - Inhibits peripheral nerve stimulation and central brain inflammatory and pain perception
  - Reduce IL-6 and PGE-2 intra-articularly
  - No increase bleeding risks, ↓opioid use
  - ? Use in bony fusion cases

Meunier et al., Acta Orthop 2009, 2007; Reuben et al., Anesth Analg 2008; O'Connor & Lysz, Drugs Today (Barc) 2008; Huang et al., BMC Musculoskelet Disord 2008

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Benefit of Selective NSAIDs
Mechanism and Efficacy in Multimodal Therapy

- NSAIDs inhibit activity of the COX enzymes to limit prostaglandin production[1]
- Meta-analysis of 60 trials to determine whether NSAIDs, COX-2 inhibitors, or acetaminophen were better at reducing morphine consumption in the postoperative setting[2]
- Affect on bony healing?

Comparison	Mean Difference in Morphine Consumption Adjusted for Baseline Morphine Consumption, mg (95% CI)
NSAID vs Acetaminophen	–0.77 (–3.75, 2.21)
COX-2 vs Acetaminophen	–1.99 (–5.24, 1.24)
COX-2 vs NSAID	–1.22 (–3.43, 1.00)

CI = confidence interval; COX-2 = cyclooxygenase-2; NSAID = nonsteroidal anti-inflammatory drug; PCA = patient-controlled analgesia; PONV = postoperative nausea and vomiting.

1. Parvizi J, et al. J Bone Joint Surg Am. 2011;93:1075-1084.
2. Maund E, et al. Br J Anesthesia. 2011;3:292-297.

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Preoperative Medications: Prevent/Minimize Initiation of Pain

- Gabapentin, pregabalin
- 300 mg or 75 mg x 1 am pre-op
- Inhibit transmission of pain in the dorsal ganglia of spinal cord
  - Decrease excitatory signal release along afferent pathway
  - Decrease glutamate (excitatory amino acid) and substance P release

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Dexamethasone
Mechanism and Efficacy in Multimodal Therapy

- Dexamethasone reduces inflammation and tissue damage
- Meta-analysis of 45 studies
  - 8 mg dose most common
  - Administered preoperatively in 28/45 studies
  - Significantly reduced VAS pain scores at 2, 24 hours
  - Reduced opioid consumption at 2 and 24 hours
  - No delayed wound healing or infection
  - Increased blood glucose observed at 24 hours
  - Anti-nausea agent

VAS = Visual Analog Scale.

Waldron NH, et al. Br J Anaesth. 2013;1(2):191-200.
Figure adapted with permission from: Waldron NH, et al. Br J Anaesth. 2013;1(2):191-200.

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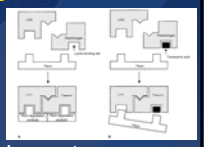
Peri-operative



- Good surgical technique
  - Minimally invasive
  - Minimize tissue trauma
- Minimize blood loss, transfusion rate
  - Tranexamic acid
  - IV, topical, oral, 50%↓ blood loss
  - 1g IV upon induction; +/- 1g at end
  - You bleed less, it hurts less

Aguilera X et al. JBJS 2013; Irwin A et al BJJ 2013; Lin et al, JBJS Br, 2012

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Nausea/Vomiting Prevention

- Pre-emptive
  - Minimize narcotics
  - Zofran 4mg IV at induction, then prn
  - Scopolamine patch (h/o motion sick, nausea)
  - Hydration
  - Decadron 6-10 mg induction; +/- POD1
- Treatment
  - Reglan
  - Hydration

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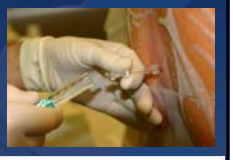
Regional Anesthesia



- Single shot spinal
  - Lower rates of cognitive dysfunction
  - Lower mortality (THA)
  - Lower mortality and LOS (TJA)
    - 11 % neuraxial
    - 14.2 % combined
    - 74.8 % general
  - Bupivacaine (avoid duramorph

Zywiel MG et al. Clin Orthop 2013; Hunt LP et al. Lancet 2013; Memtsoudis SG et al. Anesthesiology 2013

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Nerve Blocks

- Decrease nociceptive input and nerve hyper-excitability to decrease pain
- Blocks
  - Popliteal nerve
  - Saphenous nerve
  - Ankle block
  - Works best when separate block room available: efficient for surgeon

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Peri-articular Injections (PAI)

- Local anesthetic
- NSAID
- Clonidine
- Epinephrine
- Antibiotic
- Steroid

Yadeau JT et al. BJJ 2013; Ikeuchi M et al. Knee Surg Sports traumatol Arthrosc 2013; Huh, Parekh, J Surg Orth Adv 2014

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Peri-articular Injections (PAI)

- Literature review of 21 and 29 RCT in TJA
  - Peri-articular injections
    - Better pain relief
    - Lower opioid consumption
    - Better ROM
    - Less nausea and vomiting
    - No difference in LOS

Jiang J et al. J Arthroplasty 2013; Gibbs DM et al. JBJS Br 2012

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Peri-articular Injections (PAI)

- *Kim et al., FAI 2011, 60 feet*
  - HV osteotomy, inpatient, spinal
  - Ropivacaine, morphine, ketorolac, epi
    - Periosteum, deep soft tissues, subQ
  - Signif less pain at 4 hrs→POD 1, safe
- *Gadek et al., FAI 2015, 118 pts*
  - Distal 1st MT osteotomy for HV
  - Spinal + bupiv/lido, postop IV ketoprofen, tylenol
  - Decreased pain for 1st 24 hours

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Liposomal Bupivacaine

- Indicated for single-dose administration into the surgical site to produce postsurgical analgesia
- Deliver therapeutic levels of bupivacaine over 72 hrs
- Reduce opioid need w/o catheters or pumps

EXPAREL [package insert]. San Diego, CA: PACIRA; 2012.

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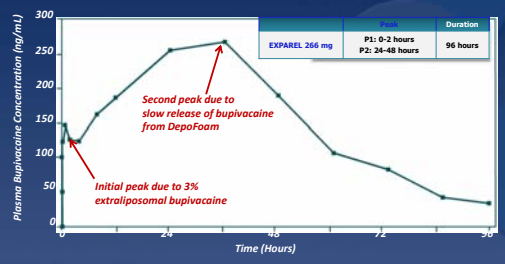
Pharmacokinetics Demonstrate Plasma Levels of Bupivacaine That Can Persist for 96 Hours



Presented at the 2009 International Anesthesia Research Society Annual Meeting; March 2009; San Diego.

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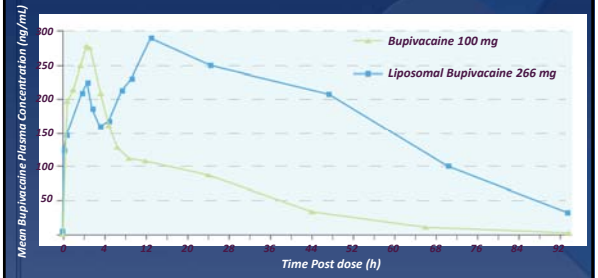
Absorption Profile* of Liposomal Bupivacaine vs Bupivacaine HCL



*After local infiltration administration in men undergoing inguinal hernia repair.

Massaro, F. Formulary. 2012;47(6):212-218,223-226.

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Injection Instructions for PAI

- Technique dependent
  - Inject slowly into multiple areas around the surgical site (min 25G)
  - Aspirate to minimize the risk of intravascular injection
  - Maximum dosage should not exceed 266 mg (1 vial)

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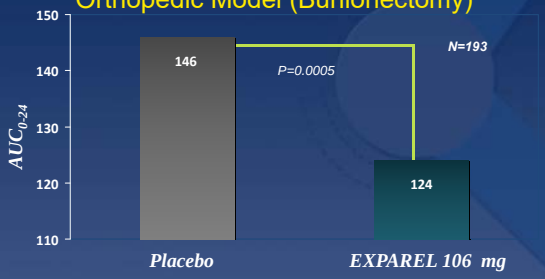
Statistically Significant Reduction in Cumulative Pain Scores at 24 Hours in Orthopedic Model (Bunionectomy)



- Fewer AEs reported with EXPAREL (59.8%) than with placebo

Golf M, et al. Adv Ther. 2011;28(9):776-788.

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Liposomal Bupivacaine in Forefoot Surgery

- *Golf et al, Adv Therapy 2011*
- 193 pts, HV
  - Greater percentage patients pain free out to 48hrs
  - Decreased time to first opioid use
  - Decreased total opioid consumption in first 24 hrs

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Effective Option in Postsurgical Pain Management

	Hemorrhoidectomy[1] (at 72 hr)	Bunionectomy[2] (at 24 hr)
Primary Endpoint Met		
Reduction in pain over extended time period	✓ $P<0.0001$	✓ $P=0.0005$
Opioid-Related Secondary Endpoints		
Total avoidance of opioid rescue	✓ $P=0.0007$	✓ $P=0.0404$
Reduced total consumption of opioid rescue	✓ $P=0.0006$	✓ $P=0.0077$
Delayed use of opioid rescue	✓ $P<0.0001$	✓ $P<0.0001$
Patient Satisfaction Secondary Endpoints		
Patient satisfaction	✓ $P=0.0007$	$P=0.08$

1. *Gorfine SR, et al. Dis Colon Rectum. 2011;54(12):1552-1559.*
2. *Golf M, et al. Adv Ther. 2011;28(9):776-788.*

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Liposomal Bupivacaine in Forefoot Surgery

- *Parekh et al., FAI 2015*
  - 20 pts, multiple forefoot procedures
  - 400mg Celecoxib preop, ankle block lido/marcaine
  - 20cc/266mg Exparel at conclusion
- Lower #narcotic pills POD1-2, lower pain scores POD1-4, decreased refills, no increase wounds

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Liposomal Bupivacaine and Cost Savings

- Exparel cost per vial: $285
- Decrease LOS, decrease adverse events
- Bupivacaine via Elastomeric Pump (>$450)
- Opioids w/IV PCA (>$500)
- ?Decreased need for peripheral nerve blocks
  - Eliminate anesthesia fees/tech or FTE
- Medicare cost per fall: $13,797-$20,450
- Steadman-Hawkins (SC): estimated savings $1735 per TKA (*Hawkins, Improving Patient Outcomes Symposium, 3/22/13)*

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Post-op Analgesia: *On a Schedule, Not PRN*

- Acetaminophen: 650 mg 6a/12n/6p
- Celebrex: 200 mg PO bid x 10d (nonfusion)
- Gabapentin or pregabalin: 300mg or 75 mg qd
- Long acting opioid (oxycontin q12 x 4d)
- Short acting opioid (percocet *prn*)
- *NO PCA*

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Use of Specific Non-pain Medications

- Muscle spasms (cyclobenzaprine)
- Nerve irritation (gabapentin)
- Nausea (metoclopromide, scopal patch)
- Vomiting (ondansetron)
- Constipation (senna-docusate)

- Ice/cooling machines

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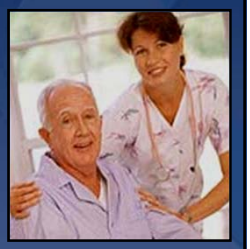
Multi-modal Pain Management: Results are Dramatic

- Little or no pain
- VAS Pain scores 0-3
- Patients alert, oriented, appropriate
- POD #1 most are sitting reading, eating breakfast
- Fewer calls!!



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Conclusions: Pain Management

- Many patients experience suboptimal pain control following orthopaedic procedures

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Conclusions: Ideal Pain Management

- Synergistic effect of multiple meds together
  - Provide effective analgesia
  - Minimize opioid use and side effects
  - Hasten mobilization and recovery
  - Decrease length of stay, reduce complications of hospital stay and immobilization
  - Reduce rates of readmission
  - Improve patient satisfaction scores

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Conclusions: Pain Management and Rapid Recovery

- Multimodal pain management continues to evolve
  - Minimize narcotics at all costs!!
- Marketing
- Benefits for you and me: thankful patients who recover faster

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Conclusions: Pain Management and Rapid Recovery

- Patient-driven outcome/satisfaction ratings
  - THE Major factor in future of healthcare delivery
  - Surgery is only part of the solution
  - HCAHPS scores (CMS)
  - Healthgrades, etc
  - MD, Hospital re-imbursement by payers
  - Ultimately…Your salary and mine

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Thank You For Your Attention

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