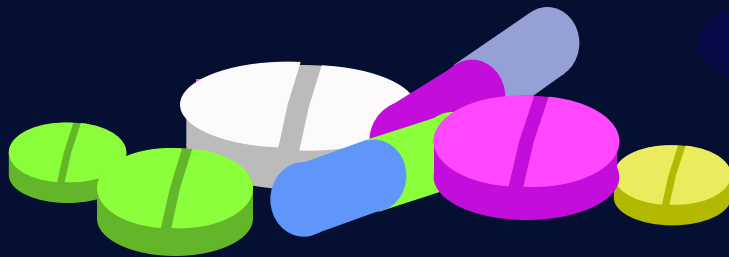


American Dental Association
PCSS-O Live Webinar
September 2, 2016, 3-4 pm ET

Pain Management in Dentistry: A Changing and Challenging Landscape



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Disclosure: Paul A. Moore

In the last ten years, Dr. Moore has served as a research consultant to several companies including Dentsply Pharmaceutical, Kodak Dental Systems, Septodont USA, Novalar Inc. and Novocol of Canada Inc. His consultations have involved pharmacovigilance of current anesthetic and analgesic products as well as research protocol development of new anesthetics for dentistry.

Additionally, Dr. Moore has also served as a principal investigator or sub-investigator for FDA required Phase II Phase III and Phase IV clinical research contracts awarded to the University of Pittsburgh by Wyeth Consumer Healthcare, Novocol of Canada Inc., St. Renatus, and Novalar Pharmaceutical Inc.



Topics of Acute Pain Management

- Trends in prescription opioid use and misuse.
- OMFS practice survey of analgesics.
- Acetaminophen: New FDA requirements.
- Adjuncts for multimodal pain management.
- Stepwise prescribing for APAP + Ibuprofen.
- Safe and Responsible Prescribing.

Heath Ledger's Overdose

- ✓ Feb 6, 2008 -- A deadly cocktail of mostly prescription drugs killed Heath Ledger.
- ✓ The deadly drug cocktail included:
 - Oxycodone, also known under brand name OXYCOTIN, a potent painkiller.
 - Hydrocodone, an ingredient in VICODIN, other painkillers, and some cough suppressants.
 - Diazepam or VALIUM, an antianxiety drug sometimes prescribed as a muscle relaxant
 - Alprazolam or XANAX, prescribed for panic attacks
 - Temazepam or RESTORIL, prescribed for insomnia

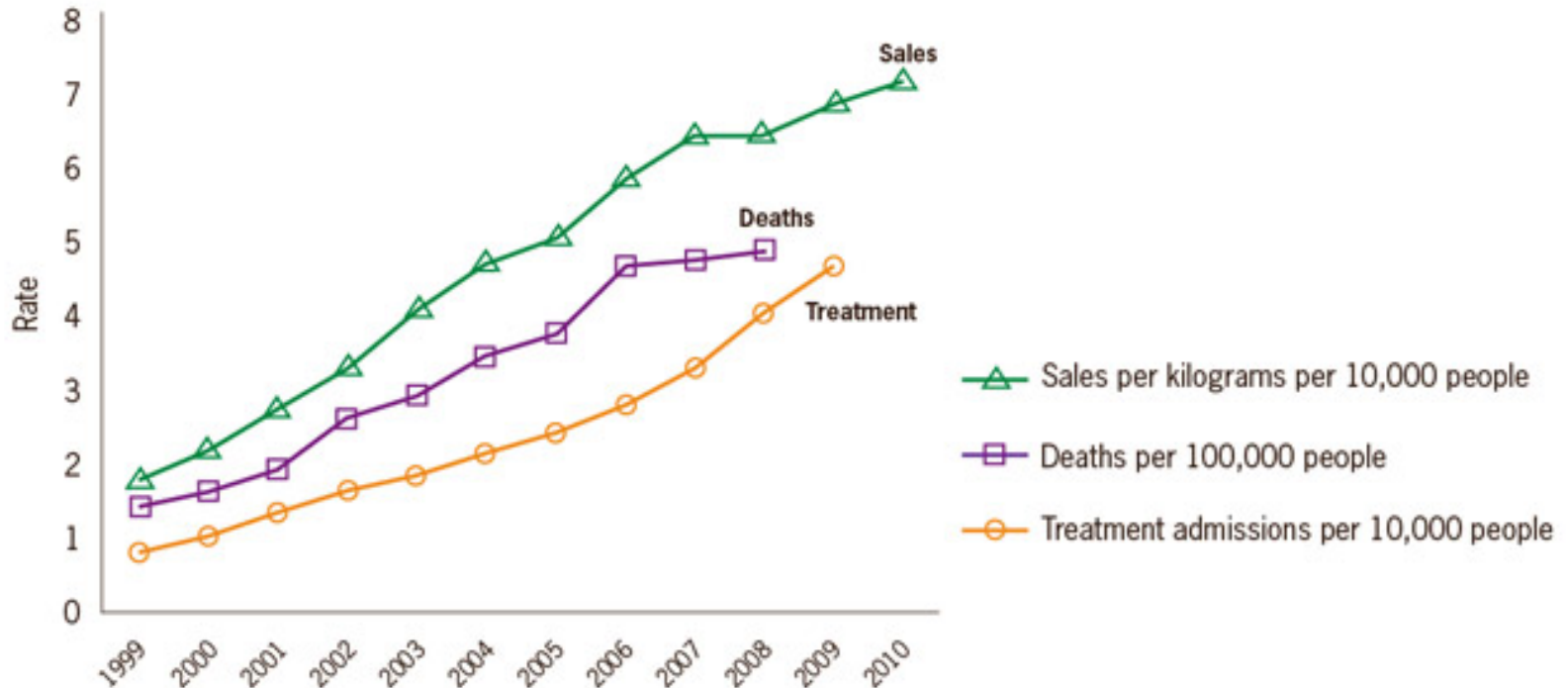
Michael Jackson's Overdose

- ✓ June 25, 2009 -- Michael Jackson died of acute propofol and benzodiazepine intoxication at his home in Los Angeles.
- ✓ His personal physician was convicted of involuntary manslaughter in 2011.
- ✓ The combination of drugs in his body included:
 - The anesthetic propofol (DIPROVAN).
 - The benzodiazepines lorazepam (ATIVAN), midazolam (VERSED) and diazepam (VALIUM).

Prince's Overdose

- ✓ April 21, 2016 – An accidental self-administered overdose of fentanyl killed Prince.
- ✓ The week before his death, Prince's plane reportedly made an emergency landing at Quad City International Airport in Moline, Illinois, as the singer was en route home from a concert in Atlanta. He was reportedly treated for: **an overdose of the opioid painkiller Percocet**

Unintentional Drug Overdose: 1999-2010



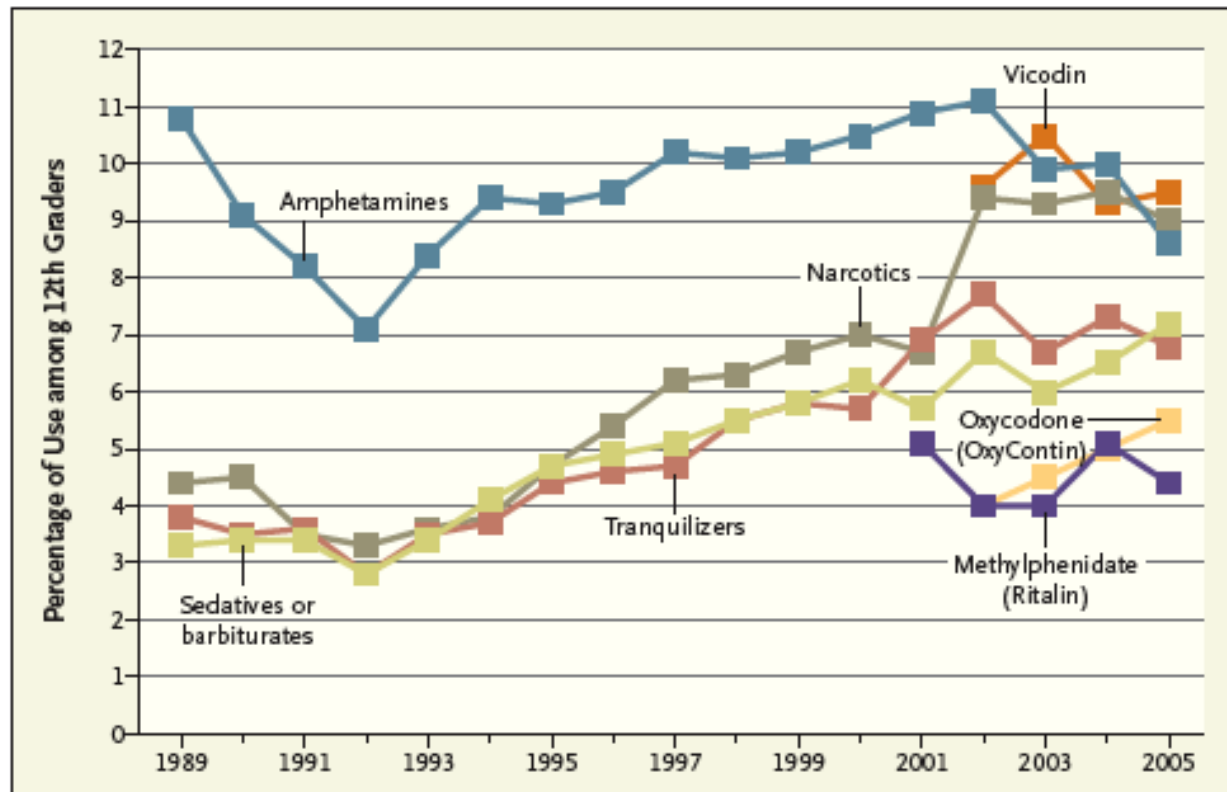
SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

Six Days of Drug Overdose: Cincinnati

- ✓ In a six day period (August 19-24, 2016) Cincinnati area experienced 174 opioid overdose reactions.
- ✓ The culprit responsible was heroin cut with a fentanyl analogue: Carfentanyl.
- ✓ Carfentanyl is 100,000 times as potent as morphine.
- ✓ Carfentanyl is used to tranquilize elephants.

Monitoring the Future

Monitoring the Future, National Survey Results on Adolescent Drug Use, 2005.



Prevalence of Use of Prescription Drugs without Medical Supervision among 12th Graders.



Trends for Opioids Misuse

- From 1997-2007, use increased from 74 mg/person to 369 mg person (500% increase).
- 174 million opioid prescriptions in 2000; 257 million opioid prescriptions in 2009.
- Prescription drugs (primarily opioids) are second to marijuana in categories of abused drugs.
- For first time users, friends and family were the primary source: “the AT&T plan”.



Trends for Opioids: Overdose

- 1.2 million emergency department visits in 2009 related to misuse of prescription drugs; now outnumbering heroin and cocaine.
- 40 deaths per day in the US resulting from opioid prescription drug misuse and abuse.
- Incidence of overdose from opioids:

5.5/100,000 in Nebraska

12.6/100,000 in Florida

JAMA 2012;307:19. (CDC).

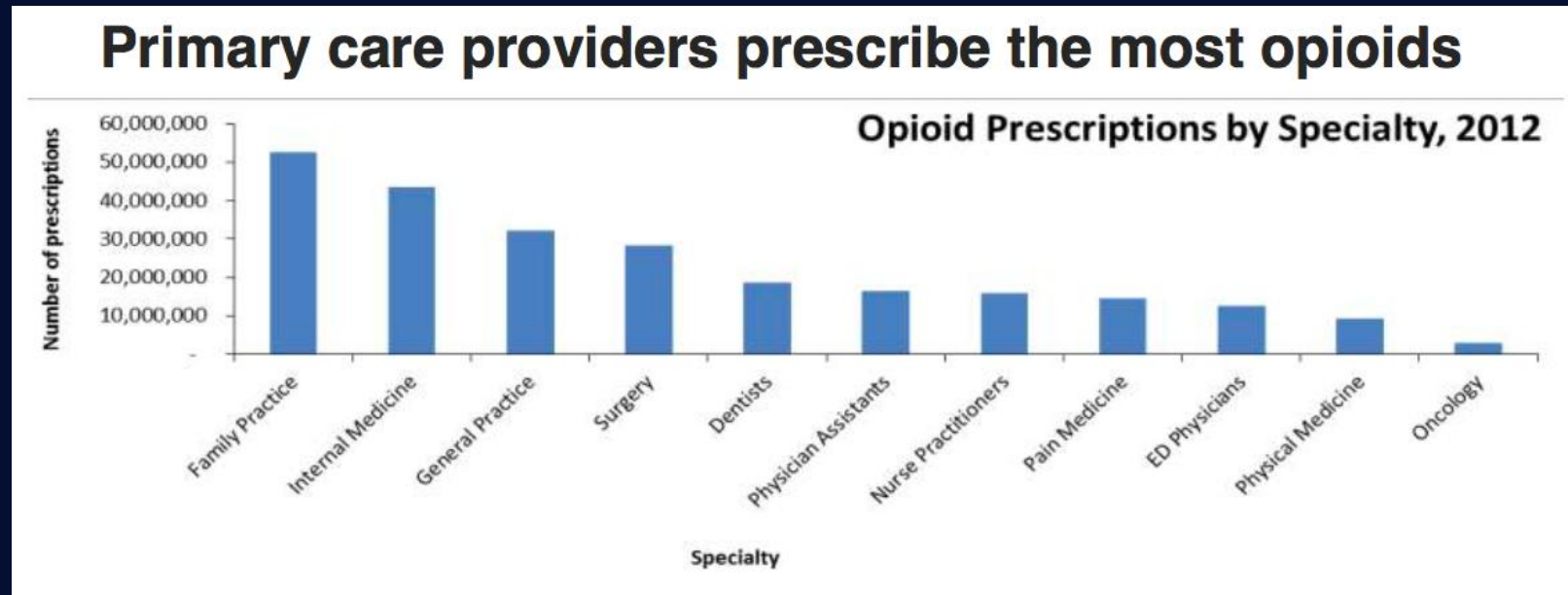


Trends: Opioid Prescribing in Dentistry

- A total of 9.4 billion units of opioids were sold in in the U.S. in 2007. (80% of total world prescriptions)
- Estimated that 15% are diverted for sale on the street.
- 12.2% of immediate-release opioids are prescribed by dentists.
- Dentist prescriptions for opioid analgesics are high for adolescents and young adults.



Opioid Prescriptions by Dentists



Dentist prescriptions:

Are for immediate release opioids (i.e. Vicodin).

Most often not refilled.

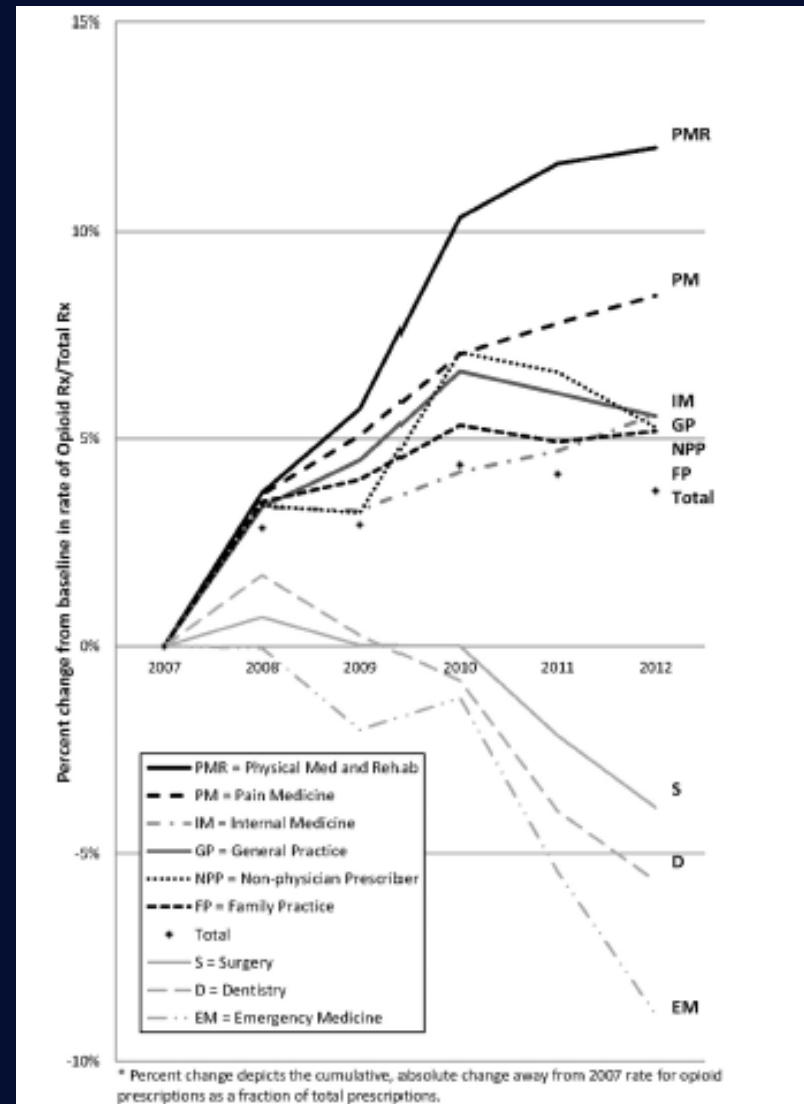
Dispensed in small quantities (16-20 pills).

Trend in prescribing rates are decreasing.

Opioid Prescriptions in Dentistry

Trends in Opioid Analgesic-
Prescribing Rates by Specialty
U.S., 2007-2012

Benjamin Levy et al.
Am J Prev Med
2015;49(3):409–413



Comprehensive National Survey

- Random national sample
- Current practicing OMFS
- 3rd molar extractions
- Pain control practices



Therapeutic Topics of Interest

✓ Anesthesia Practices

- General Anesthesia
- Intravenous Conscious Sedation
- N₂O/O₂ Inhalational Sedation
- Oral Sedation

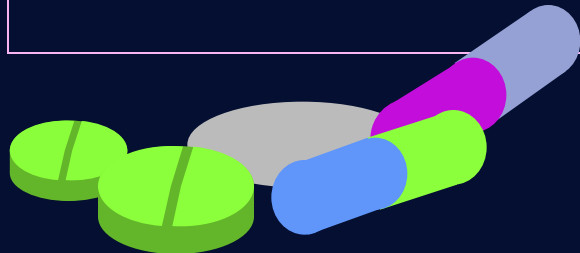
✓ Preferred Agents

- Anesthetics and Sedatives
- Local Anesthetics
 - Surgical and Post-op pain management
- Antibiotics and Corticosteroids
- Post-operative Analgesics
 - Peripherally and Centrally-Acting

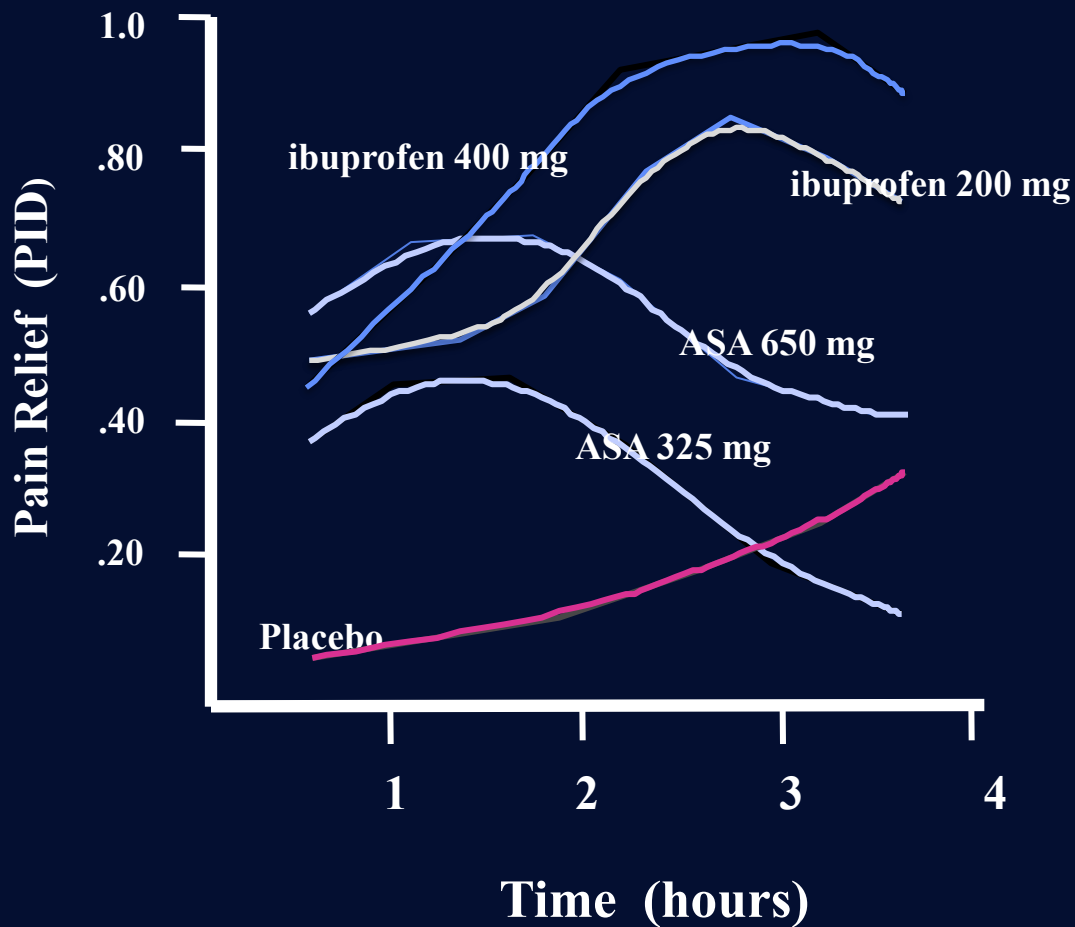
Preferred Peripherally-Acting Analgesics

“Please complete the following prescription for the **peripherally-analgesic** you have recommended most often in the past month.”

Ibuprofen (Advil, Motrin)	73.5% (312)
Rofecoxib (Vioxx)	6.1% (26)
Naproxen (Aleve, Naproxen)	4.9% (21)
Etorolac (Lodine)	4.5% (19)
Ketorolac (Toradol)	2.3% (10)
Valdecoxib (Bextra)	1.9% (8)
Acetaminophen (Tylenol)	1.7% (7)



Ibuprofen



randomized
double-blind
clinical trial
3rd molar extractions
192 subjects

Ibuprofen vs APAP

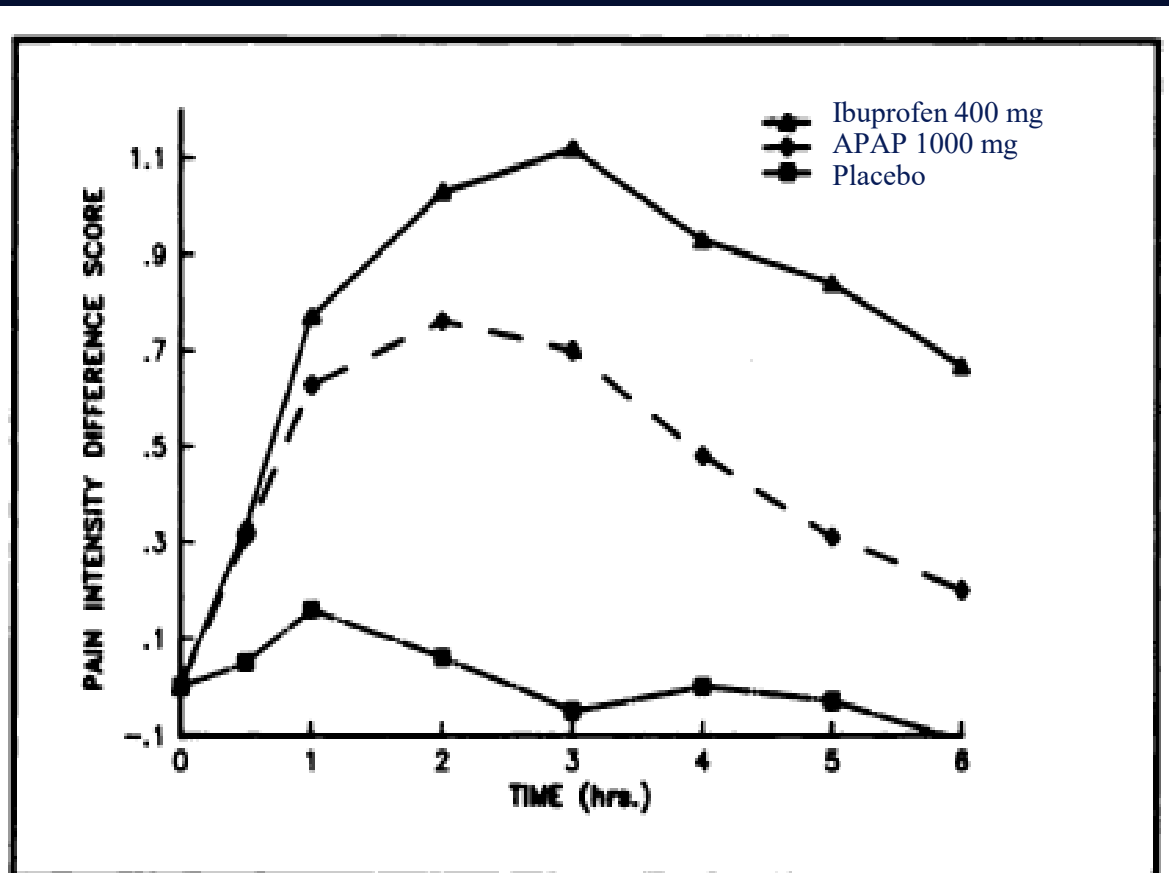
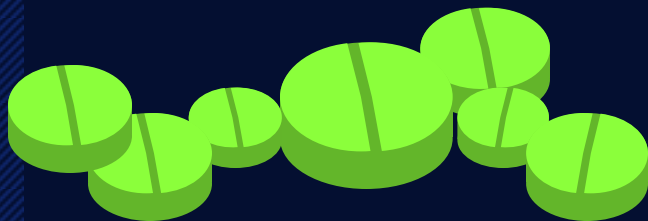


Figure 1. Mean pain intensity difference scores vs time. Pain intensity was rated on a scale of 0 = none to 3 = severe.

Centrally-Acting Analgesics

“What percentage of patients do you prescribe **centrally-acting analgesics (narcotic)** following third molar extractions? “

Rarely (1-20%)	2.9%
Sometimes (21-40%)	1.5%
Half the time (41-60%)	1.9%
Often (61-80%)	8.6%
Almost always (81-100%)	85.1%



Preferred Centrally-Acting Analgesics

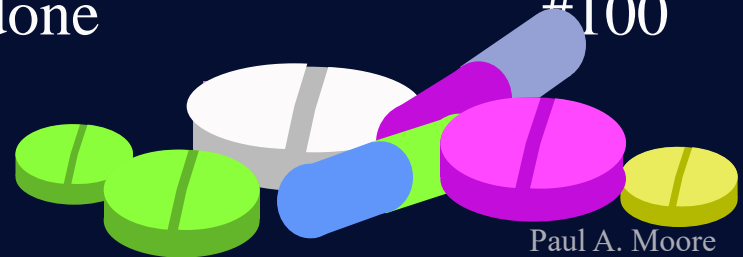
“Please complete the following prescription for the **centrally-acting analgesic** you prescribed most often in the past month.”

Hydrocodone / APAP	64.0%
Oxycodone / APAP	20.2%
Hydrocodone / ibuprofen	4.6%
Codeine / APAP	4.3%
Promethazine / meperidine	3.7%
Propoxyphene / APAP	1.2%

Prescription Analgesics

Vicodin	hydrocodone/APAP	#1
Motrin	ibuprofen	#20
Darvocet	propoxyphene/APAP	#24*
Percocet	oxycodone/APAP	#30
Ultram	tramadol	#44
Tylenol #3	codeine/APAP	#48
Naproxen	naproxen	#61
Celebrex	celecoxib	#76
Oxycontin	oxycodone	#100

Verispan Scott-Levin, SPA



Paul A. Moore



Prescribing vs Utilization

- Forty-eight patient interviews (1-day, 7-days).
- Age: 18.8 yrs. (15-30)
- Female = 22 / Males =13
- 20 Vicodin® prescribed / 8 consumed at 7-days.
- Nausea/vomiting at 7-days interview: 24%.

Welland B, Wach A, Kanar B, Sosovicka M, Cooke M, Moore PA.
Use of Opioid Pain Relievers Following Extraction of Third Molars.
Compend Cont Dent Ed 2015;36(2):2-9.



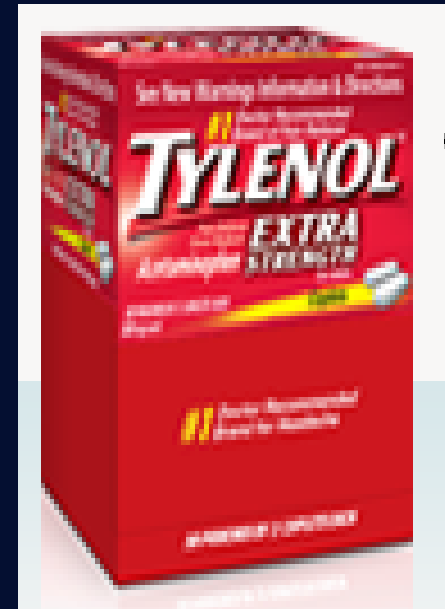
Summary: Analgesics

- OMFS's prescribe opioid analgesic almost always (85%) following third molar extraction surgery.
- Hydrocodone /APAP is the preferred combination analgesics. (efficacy, flexibility, marketing, side effects?)
- Instructions recommend “take as needed for pain” by 96% OMFS.
- Median dispensing of hydrocodone/APAP: 20 tabs (range 8-40).



Acetaminophen Toxicity

Acetaminophen has had a long history of safety, but concerns have been growing related to liver toxicity.



APAP and Acute Liver Failure

- ✓ 42% of all acute liver failures (ALF) are due to acetaminophen (APAP) overdoses.
- ✓ The majority of these APAP overdoses were unintentional (two or more APAP formulations).
- ✓ Even with treatment (N-acetylcysteine), 27% died.



Acetaminophen and Acute Liver Failure

- ✓ In Jan. 2011, FDA requested limiting APAP dose to 325 mg in opioid combination formulations such as Vicodin® and Percocet®.
- ✓ FDA labeling requirement to include a box warning for liver toxicity.
- ✓ Labeling of Tylenol® indicates a change in daily maximum of APAP from 4.0 grams to 3.0 grams.
- ✓ Decrease units for sale OTC (16 tablets in Great Britain)



Boxed Warning for Vicodin

HEPATOTOXICITY: ACETAMINOPHEN HAS BEEN ASSOCIATED WITH CASES OF ACUTE LIVER FAILURE, AT TIMES RESULTING IN LIVER TRANSPLANT AND DEATH. MOST OF THE CASES OF LIVER INJURY ARE ASSOCIATED WITH THE USE OF ACETAMINOPHEN AT DOSES THAT EXCEED 4000 MILLIGRAMS PER DAY, AND OFTEN INVOLVE MORE THAN ONE ACETAMINOPHEN -CONTAINING PRODUCT.

Tylenol OTC Labeling

- Reducing the maximum daily dose from 8 pills (4,000 mg) per day to 6 pills (3,000 mg) per day
- Changing the dosing interval from every 4-6 hours to every 6 hours.

Hydrocodone Formulations -2011

✓ Vicodan

hydrocodone 5.0mg / APAP 500 mg

hydrocodone 7.5mg / APAP 750 mg (ES)

hydrocodone 10mg / APAP 660 mg (HP)

✓ Lorcet

hydrocodone 5.0mg / APAP 500 mg (HD)

hydrocodone 7.5mg / APAP 650 mg (PLUS)

hydrocodone 10mg / APAP 650 mg (10/650)

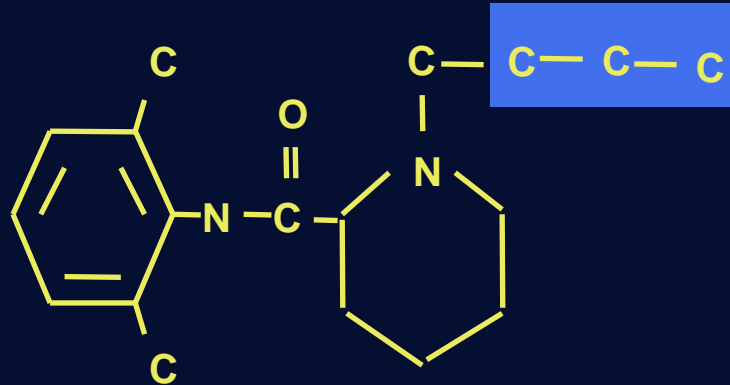
Abbott's Reformulations of Vicodin

- **Vicodin®** 5 mg hydrocodone
bitartrate / 300 mg acetaminophen
- **Vicodin ES®** 7.5 mg hydrocodone
bitartrate / 300 mg acetaminophen
- **Vicodin HP®** 10 mg hydrocodone
bitartrate / 300 mg acetaminophen

Darvocet and Darvon Withdrawal

- ✓ Mild opioid analgesic: Schedule IV
- ✓ Propoxyphene, the active component, puts patients at risk of potentially serious or fatal heart rhythm abnormalities.
- ✓ Propoxyphene has a poor benefit to risk profile.
- ✓ November 2010, withdrawn by Elli Lilly.

Bupivacaine



- Marketed as Marcaine® and Vivacaine®
- Provides prolonged duration of soft tissue anesthesia to delay the postoperative pain (6-8 hours).
- 0.5% bupivacaine, 1:200,000 epinephrine.
- Onset time is longer (8 min. vs 4 min.) than other LA drugs b/c of elevated pKa
- Long duration due to binding to tissue proteins.

Local Anesthetics for Oral Surgery

“Which one of the following local anesthetics do you administer most frequently for anesthesia when extracting third molars?”

Local Anesthetic Formulation	Frequency
2% lidocaine, 1:100,000 epinephrine	70.4%
0.5% bupivacaine, 1:200,000 epinephrine	11.3%
4% articaine, 1:100,000 epinephrine	7.3%
4% prilocaine, 1:200,000 epinephrine	3.1%
2% mepivacaine, 1:20,000 levonordefrin	1.9%
2% lidocaine, 1:50,000 epinephrine	1.8%
3% mepivacaine	0.7%
1.5% etiodocaine, 1:200,000 epinephrine	0.5%
4% prilocaine	0.2%
Do not use local anesthetics	2.8%



Long-Acting Local Anesthetics

“How often do you use long-acting local anesthetics to manage the post-operative pain of third molar extractions? **Check ONE box**”

Never	20.2%
Rarely	19.6%
Sometimes	8.0%
Half the time	5.7%
Often	10.6%
Almost always	35.8%

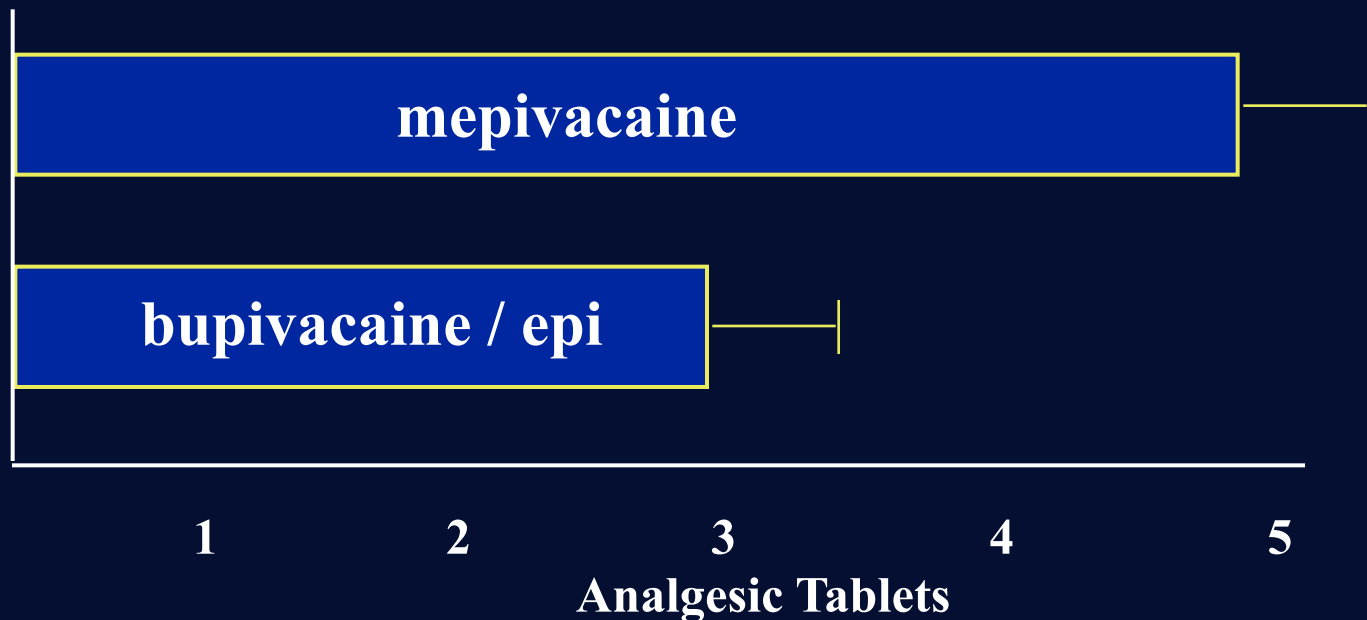
“95% of OMFS selected 0.5% bupivacaine, 1:200,000 epinephrine”



Post-Extraction Pain



Analgesics Following Third Molar Extractions



Trieger N and Gillen GH. Anesth Prog 20:23-27, 1979.



Ibuprofen Pretreatment

Pretreatment	Pain onset (min)	Severity		
		Severe	Moderate	Mild
Placebo	137 ± 8	16	29	0
Ibuprofen	238 ± 20	8	34	3

Dionne and Cooper; Oral Surg 45:851

Corticosteroid Use: 3rd molars

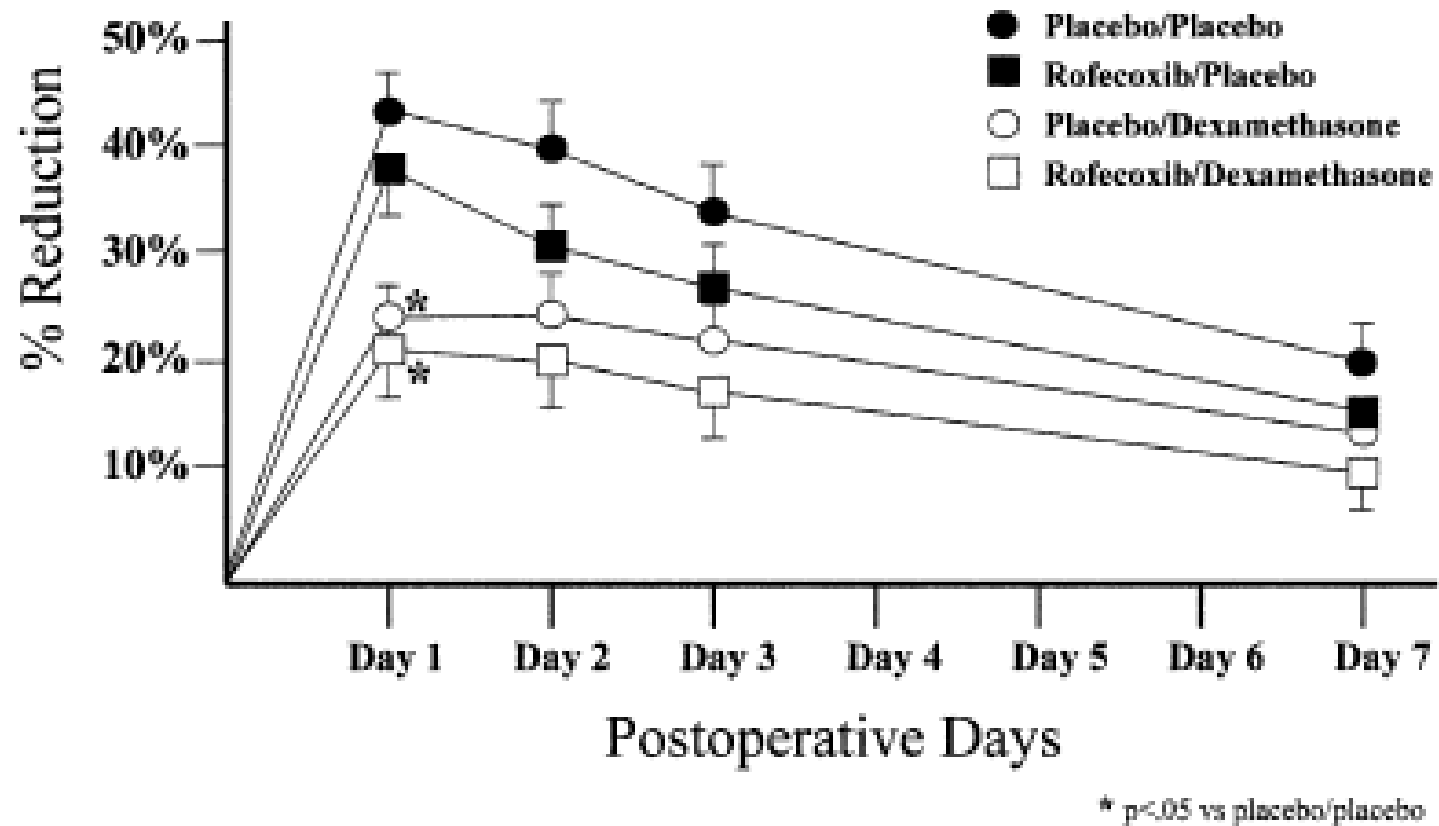
“How often do you use corticosteroids as part of your post-operative management?”

Never	20.0%
Rarely	7.9%
Sometimes	6.2%
Half the time	5.1%
Often	22.8%
Almost always	38.0%

“90.2% of OMFS selected dexamethasone”

Dexamethasone and Third Molar Surgery

Trismus Following Third Molar Extractions



Dexamethasone and Third Molar Surgery

Table III. Pain relief measures

<i>Treatment Groups</i>	<i>Group 1</i>	<i>Group 2</i>	<i>Group 3</i>	<i>Group 4</i>
<i>Preoperative Tx</i>	<i>Placebo</i>	<i>Rofecoxib</i>	<i>Placebo</i>	<i>Rofecoxib</i>
<i>Intraoperative Tx</i>	<i>Placebo</i>	<i>Placebo</i>	<i>Dexamethasone</i>	<i>Dexamethasone</i>
Time of first analgesic				
Mean (\pm SE) hours after surgery (ANOVA; $F = 1.32$, $P = ns$)	3.3 (\pm 0.9)	5.0 (\pm 1.2)	3.8 (\pm 0.9)	5.6 (\pm 1.0)
Pain at first analgesic				
Mean Visual Analogue Scale (SE) (ANOVA; $F = 5.14$, $P > .0066$)	60.0 (7.5)	46.6 (9.5)	48.9 (7.0)	18.3 (8.0)**
Categorical scale				
None	0	0	0	1*
Mild	1	0	3	5
Moderate	4	5	5	1
Severe	3	0	1	0
(Chi square = 18.4, $P > .03$)				

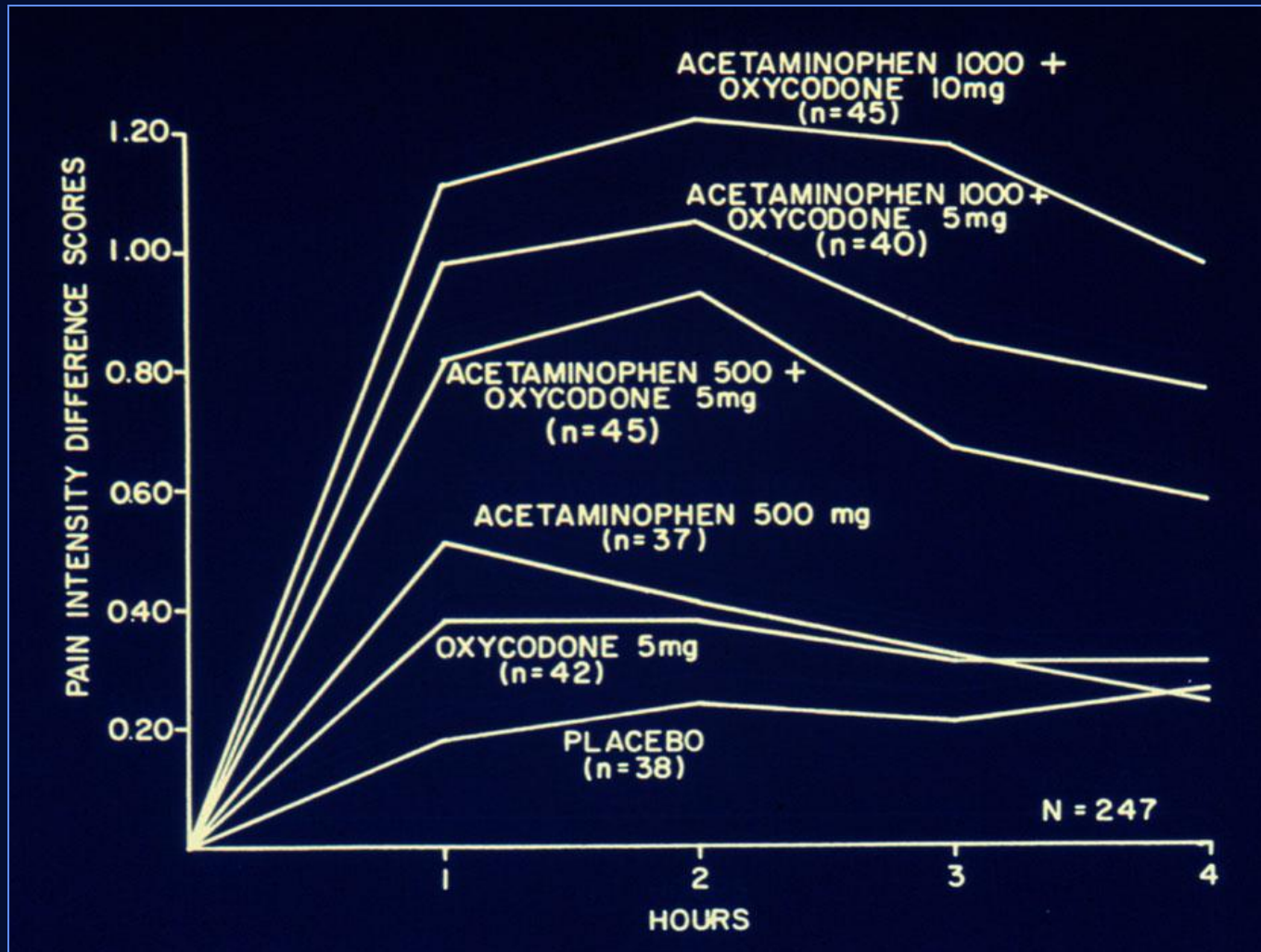
* $P < .05$ compared to Group 1 (placebo/placebo).

** $P < .05$ compared to Groups 1, 2, and 3.

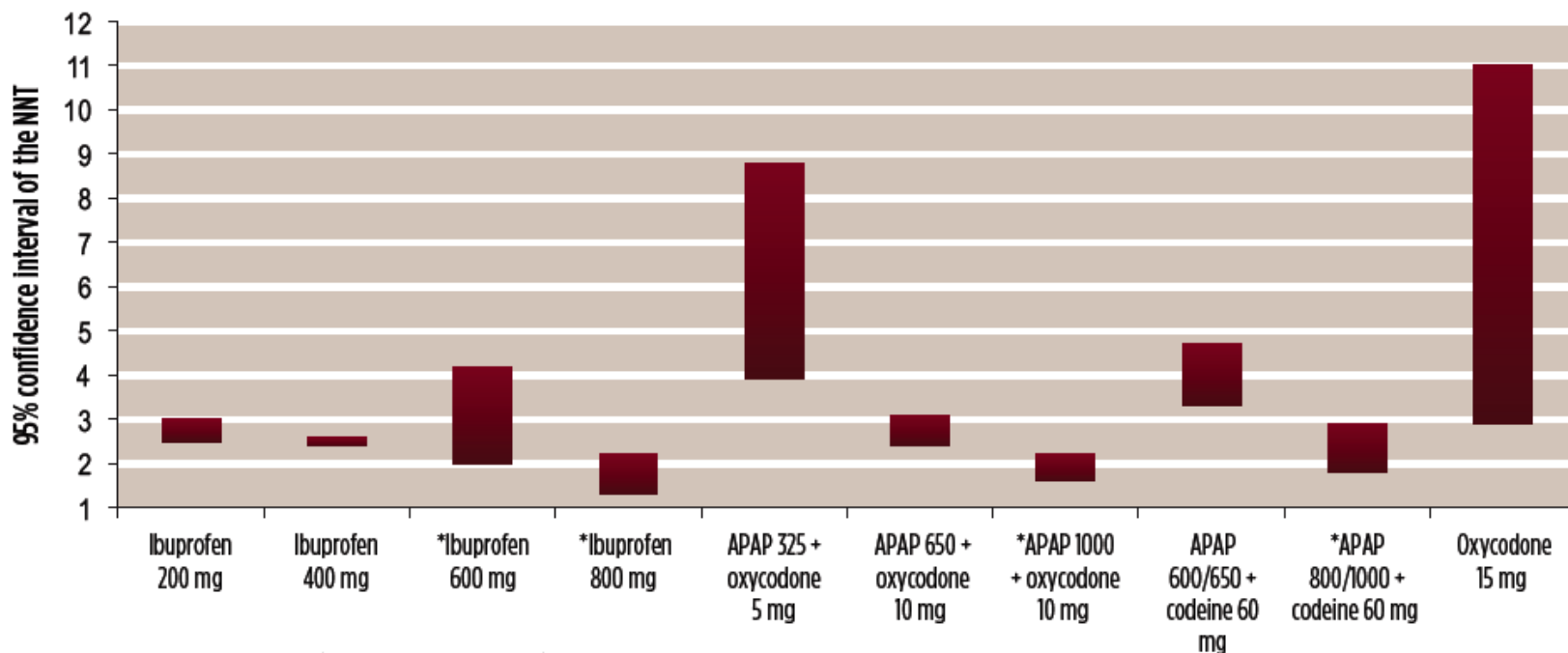
Multimodal Postoperative Pain Management

- ✓ Ice, soft diet and rest.
- ✓ Long-acting local anesthetics i.e. Marcaine.
- ✓ Primary reliance on NSAIDs (ibuprofen, naproxen) when managing dental postoperative pain.
- ✓ Steroids (dexamethasone) as an anti-inflammatory agents limit trismus and swelling.
- ✓ Use of NSAID's pre-emptively.

Oral Surgery Model: Opioid Combinations



Ibuprofen vs. APAP/Oxycodone

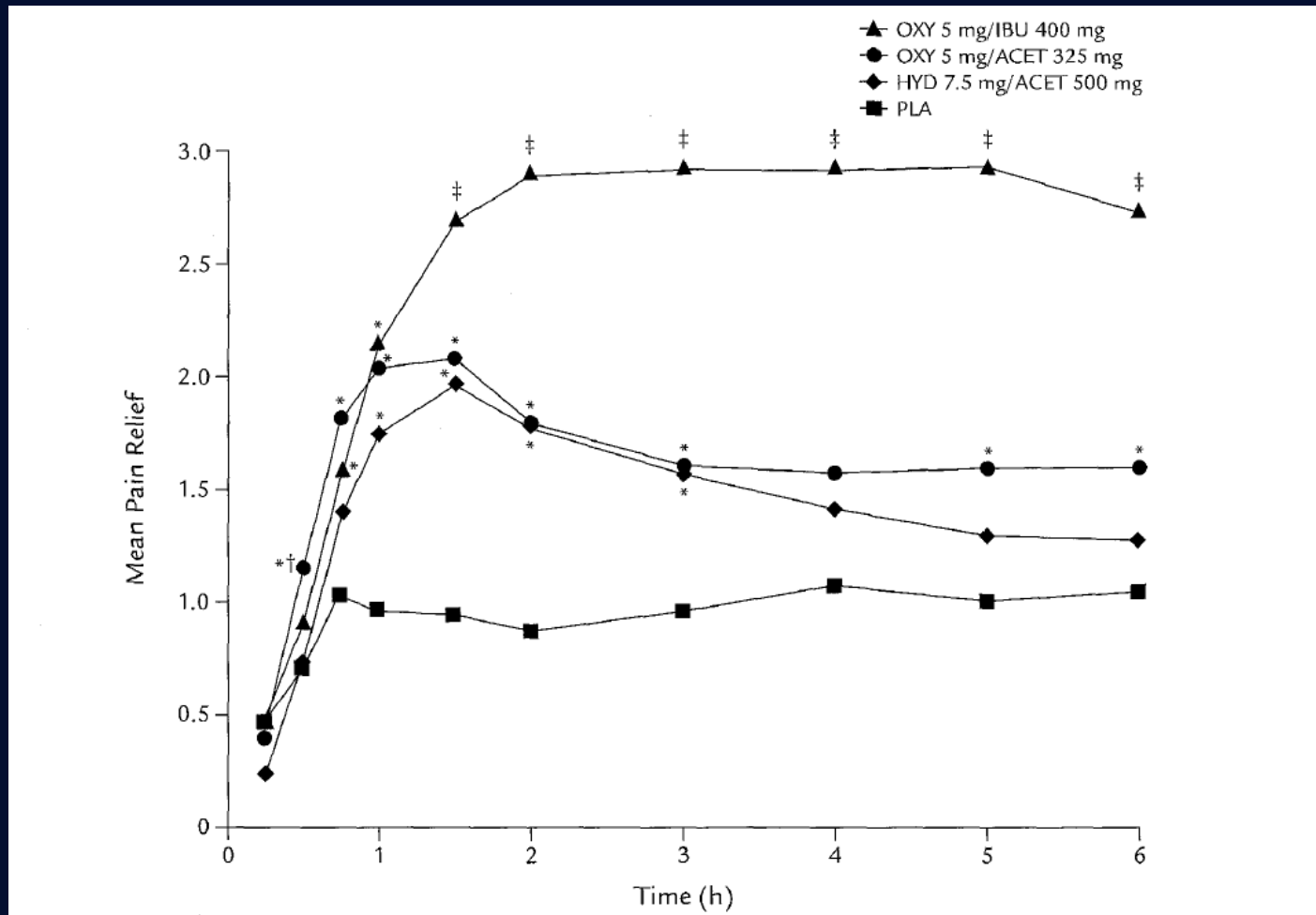


*Based on only 1 to 3 studies (each with less than 300 patients)

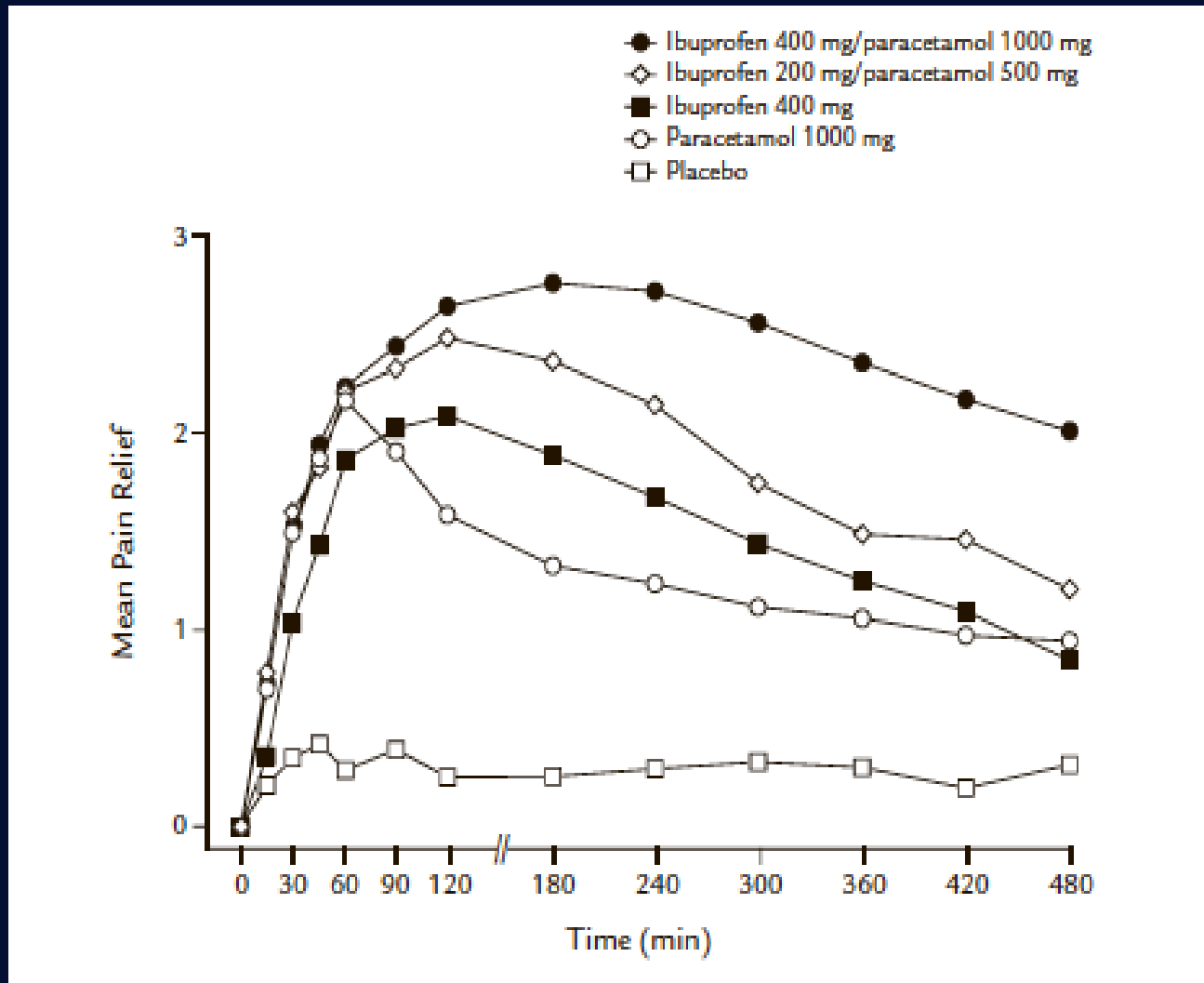
OTC Analgesic Comparisons

	Aspirin	Acetaminophen	Ibuprofen
Analgesic	+++	+++	++++
Antipyretic	+++	+++	+++
Anti-inflammatory	+++	+	+++

Ibuprofen-Opioid Combination



Ibuprofen and APAP



Ibuprofen and APAP

Table IV. Onset and duration of analgesic efficacy in the 5 treatment groups (intent-to-treat population) of patients undergoing surgical removal of impacted molars. Data are mean minutes (number of patients meeting the end point), except as indicated.

Kaplan-Meier End Point*	Ibuprofen 400 mg/ Paracetamol 1000 mg (n = 67)	Ibuprofen 200 mg/ Paracetamol 500 mg (n = 33)	Ibuprofen 400 mg (n = 69)	Paracetamol 1000 mg (n = 34)	Placebo† (n = 31)
Time to PID ≥ 1 Efficacy ranking (A–D)	38.0 (60) A	51.2 (31) A, B	80.1 (59) B	61.4 (30) A, B	157.3 (7) C
Time to first confirmed perceptible pain relief Efficacy ranking (A–D)	23.2 (52) A	21.8 (26) A	48.6 (48) B	24.8 (18) B	97.5 (2) C
Time to first meaningful pain relief Efficacy ranking (A–D)	93.6 (52) A, B	74.0 (26) A	123.9 (47) A, B	141.0 (18) B	132.8 (2) C
Time to pain half gone Efficacy ranking (A–D)	69.3 (65) A	85.9 (32) A, B	113.7 (65) B	135.2 (32) B	229.1 (30) C
Time to use of rescue medication Efficacy ranking (A–D)	376.3 (21) A	328.5 (20) B	296.2 (47) B	261.2 (24) B	144.4 (28) C

PID = pain intensity difference.

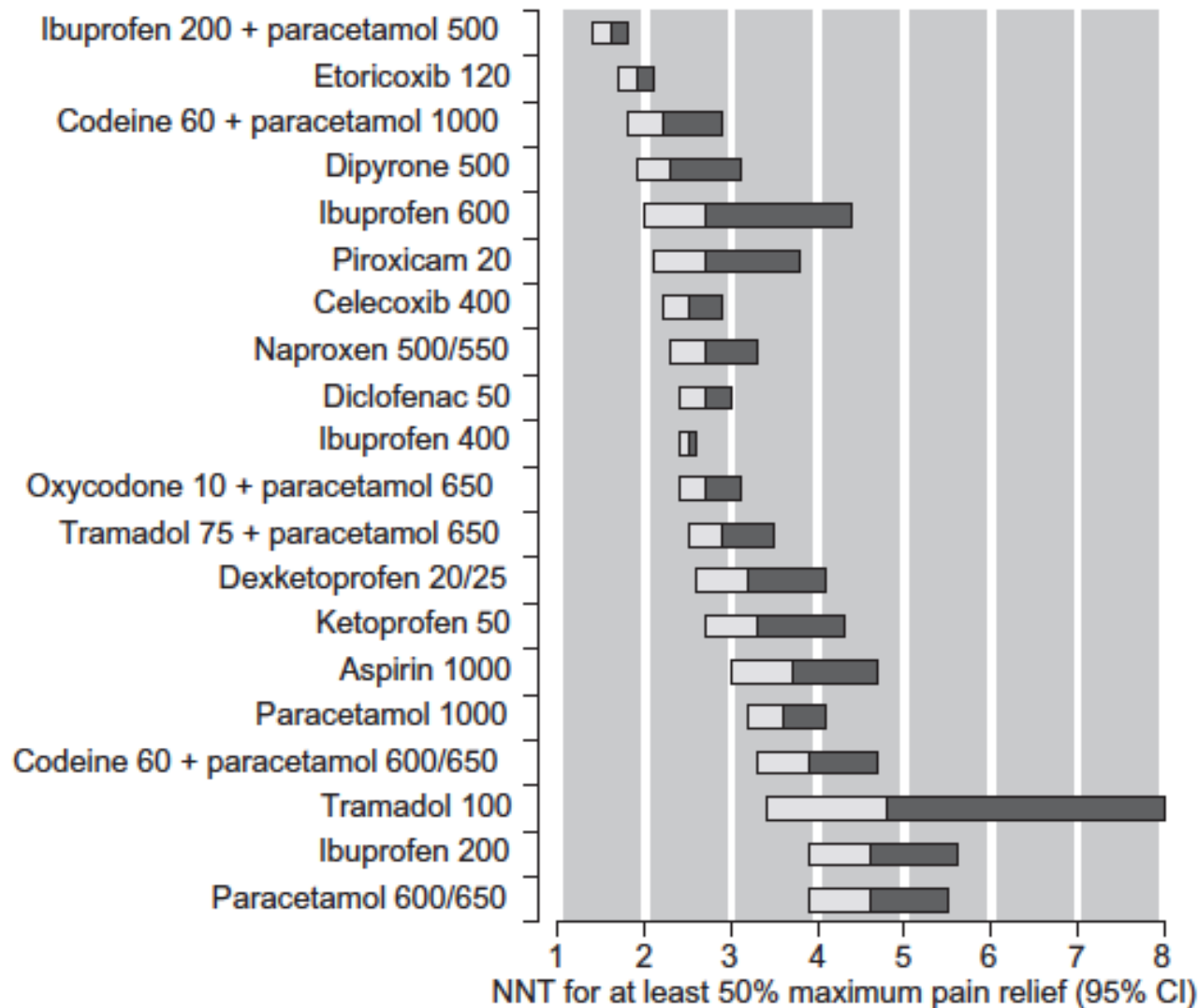
*Treatments were ranked A to D, with A denoting the most effective treatment; the same letter for 2 treatments means no significant difference between treatments. No comparison was made between ibuprofen alone and paracetamol alone, so they are indicated as not significantly different.

Ibuprofen and APAP

Table V. Frequency (>5% of patients) of adverse events (AEs) in the 5 treatment groups of patients undergoing surgical removal of impacted molars. Data are number (%).

AE	Ibuprofen 400 mg/ Paracetamol 1000 mg (n = 67)	Ibuprofen 200 mg/ Paracetamol 500 mg (n = 33)	Ibuprofen 400 mg (n = 69)	Paracetamol 1000 mg (n = 34)	Placebo (n = 31)
Any AE	38 (56.7)	14 (42.4)	39 (56.5)	24 (70.6)	21 (67.7)
Treatment-related AE	10 (14.9)	6 (18.2)	19 (27.5)	12 (35.3)	13 (41.9)
Severe AE	11 (16.4)	6 (18.2)	14 (20.3)	11 (32.4)	11 (35.5)
Nausea	15 (22.4)	7 (21.2)	18 (26.1)	10 (29.4)	11 (35.5)
Vomiting	9 (13.4)	4 (12.1)	13 (18.8)	10 (29.4)	8 (25.8)
Headache	5 (7.5)	1 (3.0)	9 (13.0)	7 (20.6)	2 (6.5)
Dizziness	2 (3.0)	1 (3.0)	6 (8.7)	7 (20.6)	3 (9.7)

NNTs for Analgesic Agents



NNTs for Dental Analgesics

Drug Formulation	Trials/Subjects	NNT (C.I.)
Aspirin 600/650 mg	45/3581	4.5 (4.0-5.2)
Aspirin 1,000 mg	4/436	4.2 (3.2-6.0)
Acetaminophen 1,000 mg	19/2157	3.2 (2.9-3.6)
Ibuprofen 200 mg	18/2470	2.7 (2.5-3.0)
Celecoxib 400 mg	4/620	2.5 (2.2-2.9)
Ibuprofen 400 mg	49/5428	2.3 (2.2-2.4)
Oxycodone 10 mg plus Acetaminophen 650 mg	6/673	2.3 (2.0-6.4)
Codeine 60 mg plus APAP 1000 mg	26/2295	2.2 (1.8-2.9)
Naproxen 500/550 mg	5/402	1.8 (1.6-2.1)
Ibuprofen 200 mg plus Acetaminophen 500 mg	2/280	1.6 (1.4-1.8)

Stepwise Guidelines

Mild Pain

Ibuprofen 200-400 mg
q 4-6 hours: as needed (p.r.n.) pain

Mild-Moderate Pain

Ibuprofen 400-600 mg
q 4-6 hours: fixed interval for 24 hours

Moderate - Severe Pain

Ibuprofen 400-600 mg plus APAP 500 mg
q 6 hours: fixed interval for 24 hours

Severe Pain

Ibuprofen 400 mg plus APAP 650/hydrocodone 10 mg
q 6 hours: fixed interval for 24-48 hours

Issues in Therapeutics

- ✓ Changes in drug therapy for post-operative dental pain management.
 - No longer prescribing Darvocet or Tylenol #3.
 - Limiting dose of APAP in combination analgesics.
 - Long-acting local anesthetics i.e. Marcaine
 - High efficacy of NSAIDs in dental post-op pain.
 - Steroids as an antiemetic and an anti-inflammation.
 - Prophylactic NSAID's.
 - APAP-Ibuprofen
- ✓ Balancing pain management and potential misuse.

National Issues in Opioid Therapeutics

- ✓ Expand take-back programs.
- ✓ Educational requirements for DEA registration.
- ✓ REMS: Opioid Risk Evaluation and Mitigation Strategies.
- ✓ Expand dental school accreditation curriculums in anesthesia and pain control.
- ✓ PDMPs: Electronic State sponsored prescription drug monitoring programs.
- ✓ Revise opioid formulation DEA scheduling.

Provider Issues in Opioid Therapeutics

- ✓ Limiting prescriptions with fewer units of opioids.
(No refills, 8 units?, 20 units?, 40 units?)
- ✓ Counsel parents and patients of dangers.
This may be our most important “teaching opportunity for first time users of anesthetics and analgesic drugs”
- ✓ Parent responsibility as the “gatekeeper” to monitor pain and analgesia needs.
- ✓ Recommend strategies to secure prescriptions.
- ✓ Indicate DEA drug take-back programs.
- ✓ Describe procedures for disposal of unused drug.



Disposal of Prescription Drugs

Take them out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through your trash. Put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag.

- Cat litter
- Coffee grinds
- Take back programs
- Flush it done!



Prescription Drug Disposal: Flushing

Fentanyl: Duragesic, patch (extended release)

Methylphenidate

Meperidine: Demerol, tablets

Diazepam

Hydromorphone HCl: Dilaudid, tablets, oral liquid

Methadone: Dolophine Hydrochloride, tablets

Morphine: Embeda, capsules (extended release)

Hydromorphone Hydrochloride

Methadose, tablets

Morphine Sulfate, tablets (immediate release)

Oxycontin, tablets

Percocet, tablets & Percodan, tablets

APAP /Ibuprofen Reviews

Moore PA and Hersh EV.

Combining Ibuprofen and Acetaminophen for Acute Postoperative Pain Management: Translating Clinical Research to Dental Practice.

J Am Dent Assoc 2013;144(8):898-908.

Guggenheimer J and Moore PA.

Therapeutic applications and risks associated with acetaminophen: a review and update. J Am Dent Assoc 2011;142(12):38-44.

Moore PA and Hersh EV.

Postoperative Pain Management in Dentistry: Five Strategies to Assure Safe and Effective Care. Inside Dentistry April 2015.

Moore PA, Dionne RA, Cooper SA, and Hersh EV.

Why Do We Prescribe Vicodin? J Am Dent Assoc 2016;147(7):530-533.

Request at: pam7@pitt.edu

Paul A. Moore



Questions / Comments



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Providers' Clinical Support System for Opioid Therapies (PCSS-O) Training

PCSS-O is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org

For questions, email: pcss-o@aaap.org

Visit us on Twitter: [@PCSSProjects](https://twitter.com/PCSSProjects)

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Webinar Evaluations (Post and 30-Day)

Each PCSS-O partner organization is asked to distribute a post and 30-day evaluation to participants for their completion.

Participants in today's webinar will be emailed the following link to complete their evaluation:

<http://www.cvent.com/d/fvq0mw>

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