EVMS Emergency Medicine Journal Club
Therapy Worksheet

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CITATION: Chang Et al. Effect of a single dose of oral opioid and non-opioid analgesics on acute extremity pain in the emergency department

A. What is being studied? (Answer below)	Comments
1. Study Objective	"To compare the degree of pain reduction 2 hours after ingestion of 4 oral combination analgesics" ibuprofen/acetaminophen vs oxycodone/acetaminophen vs hydrocodone/acetaminophen vs codeine/acetaminophen in treating acute extremity pain.
2. Study Design	Double-blinded RCT at 2 urban center EDs
3. Inclusion Criteria	Adults aged 21-64 presenting with acute onset pain from the shoulder down or hip down that was judged to require radiographic imaging (physician dependent) (used as proxy for more severe injury)
4. Exclusion Criteria	Past use of methadone, chronic pain condition, hx of adverse reaction to study medications, use of opioids in last 24 hours, use of ibuprofen/acetaminophen in last 8 hours, pregnant, breastfeeding, hx of PUD, recreational narcotic use, medical condition affecting metabolism of study meds (hepatic or renal disease, thyroid disease, Addison, Cushing), presence of medicine that might interact with 1 of the study medications
5. Interventions Compared	400mg ibuprofen + 1000mg acetaminophen vs 5mg oxycodone + 325mg acetaminophen vs 5mg

	hydrocodone + 300mg acetaminophen vs 30mg codeine + 300mg acetaminophen
6. Outcomes Evaluated	NRS (0-10) pain score at 1 and 2 hours **Primary**: between-group difference in mean change in NRS pain score at 2 hours **Secondary**: between-group difference in mean change in NRS pain score at 1 hour and responses to a 4 point Likert scale that was left out in the end. Post-hoc: Proportion of patients receiving rescue analgesics, total amount of analgesics in morphine equivalent units, patients with documented fractures and reported scores of 10.
B. Are the results of the study valid? Answer questions below	
1. Were patients randomized?	Yes. Using a block of 8 computer generated process.
2. Was randomization concealed (Blinded)	Yes, performed by pharmacist, nurses pulled packets from Pyxis and all meds were in 3 similar opaque capsules.
3. Were patients analyzed in the groups to which they were randomized?	Yes, data was analyzed using an intention to treat model. Only 1 patient in each group required ITT assessment.
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. See table 1
C. Did experimental and control groups retain a similar prognosis after the study started (answer the questions below)?	
1. Were patients aware of group allocation?	No, everyone got same 3 opaque capsules
2. Were clinicians aware of group allocation?	No.

3. Were outcome assessors aware of group allocation?	Does not say specifically, but would guess that they were.
4. Was follow-up complete?	Yes – 99% of participants had both data points.
D. What were the results?	
1. How large was the treatment effect? (difference between treatment and control group).	No significant difference in pain reduction between the 4 groups
2. How precise was the estimated treatment effect at a 95% confidence interval?	The overall mean NRS pain score decreased by 4.3 (95% CI, 3.6 to 4.9) which represents 49.4% reduction. Ibuprofen +APAP: 4.3 (95% CI, 3.6 to 4.9) Oxycodone. + APAP 4.4 (95% CI, 3.7 to 5.0) Hydrocodone. + APAP 3.5 (95% CI, 2.9 to 4.2) Codeine + APAP 3.9 (95%CI, 3.2 to 4.5)
D. How can I apply the results to patient care	
IV. Were the study patients similar to my patients?	Probably. Montefiore is similar to Norfolk general though more Hispanics there. Other than cultural differences, seems applicable to any young, relatively healthy person with acute extremity pain.
1. Were all clinically important outcomes considered?	Could have considered discharge pain control. No discharge or post ED visit assessments.
2. Are the likely treatment benefits worth the potential harms and costs?	Likely yes, though no analysis of harm conducted.

Limitations:

Short duration of follow up, Significant level of rescue analgesia use without any clear indication of why it was given or what type of injury received it, no adverse event information collected, study design was for a fast track/split flow type setting so not clear if it translates to the MTA setting, does not look at what patients were discharged on

Clinical Bottom Line:

Well controlled, blinded study that attempted to minimize experimental bias.
Ibuprofen/acetaminophen is a viable option in the relatively healthy individual presenting with acute onset extremity pain.