Compounded Topical Analgesics

Scientific & Clinic Experiences

Jeffrey Fudin, PharmD, FCCP, FASHP, FFSMB

Chief Executive Officer & Chief Medical Office, REMITIGATE LLC

Clinical Pharmacy Specialist & PGY2 Pain Residency Director
Stratton VA Medical Center (WOC)

Adjunct Associate Professor

Albany College of Pharmacy & Health Sciences &

Western New England University College of Pharmacy

Disclosures

Affiliation	Role	Therapeutic Area
AcelRx Pharmaceuticals	Advisory Board	Acute pain
Acutis Diagnostics, Inc	Speaker	Laboratory, toxicology
Astra Zeneca	Speakers Bureau	Opioid-induced constipation (OIC)
BioDelivery Sciences International	Consultant	Pain therapeutics
Daiichi Sankyo	Advisory Board, Speakers Bureau	Pain therapeutics
Firstox Laboratories	Consultant	Laboratory, toxicology
GlaxoSmithKline (GSK)	Advisory Board	Anesthetics, Pain therapeutics
Quest Diagnostics	Advisory Board	Laboratory, toxicology
Scilex Pharmaceuticals	Advisory Board	Pain therapeutics
Salix Pharmaceuticals	Advisory Board	Opioid withdrawal, OIC

Objectives

- Describe recent literature and outcomes regarding topical compounded analgesics
- Understand the process required to compound various analgesics (selection of base, solubilities, absorptive properties)
- Compare and contrast pharmacology of selected drugs
- Explain the practical pitfalls and attributes of topical products

Compounded Topical Pain Creams to Treat Localized Chronic Pain

- Objective: To determine the efficacy of compounded creams for chronic pain.
  - Randomized controlled trials of 3 interventions.
    - Neuropathic, nociceptive, mixed (133 in each arm)
- ~400 patients with localized pain classified by each
- Walter Reed National Military Medical Center

Brutcher RE, Kurihara C, Bicket MC, Moussavian-Yousefi P, Reece DE, Solomon LM, Griffith SR, Jamison DE, Cohen SP. Compounded Topical Pain Creams to Treat Localized Chronic Pain: A Randomized Controlled Trial. Annals of internal medicine. 2019 Feb 5.

Participants and Recruitment

- 1144 patients
- 745 not randomized
  - logistic reasons (652 total)
    - Average pain score <4
    - Previous failure on topicals, dementia, or psychiatric comorbidity
  - Eligible but declined to participate (93)
- 1144 – (652+93) = 399
- 399/3 = 133 participants in each group

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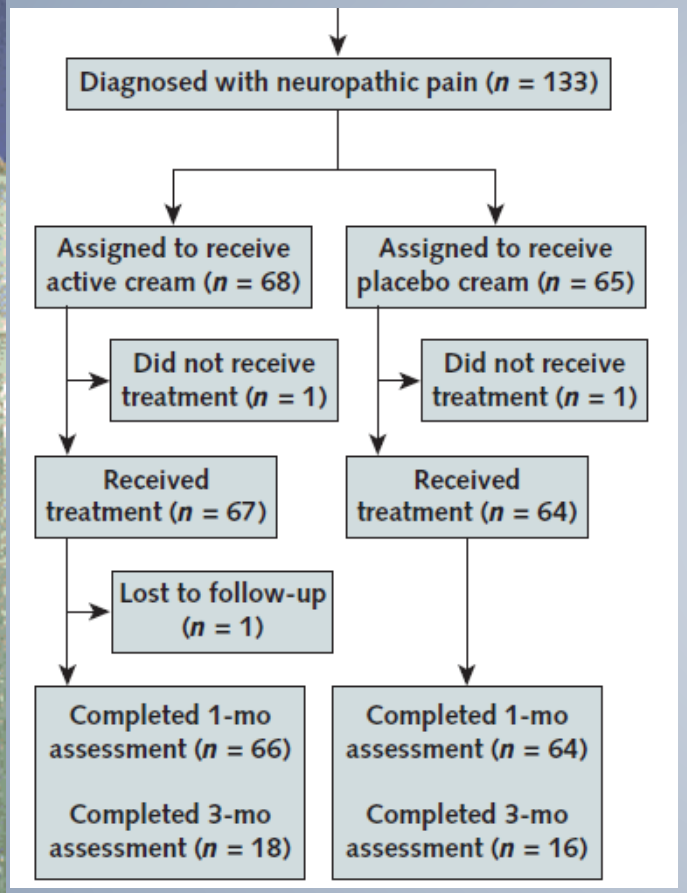
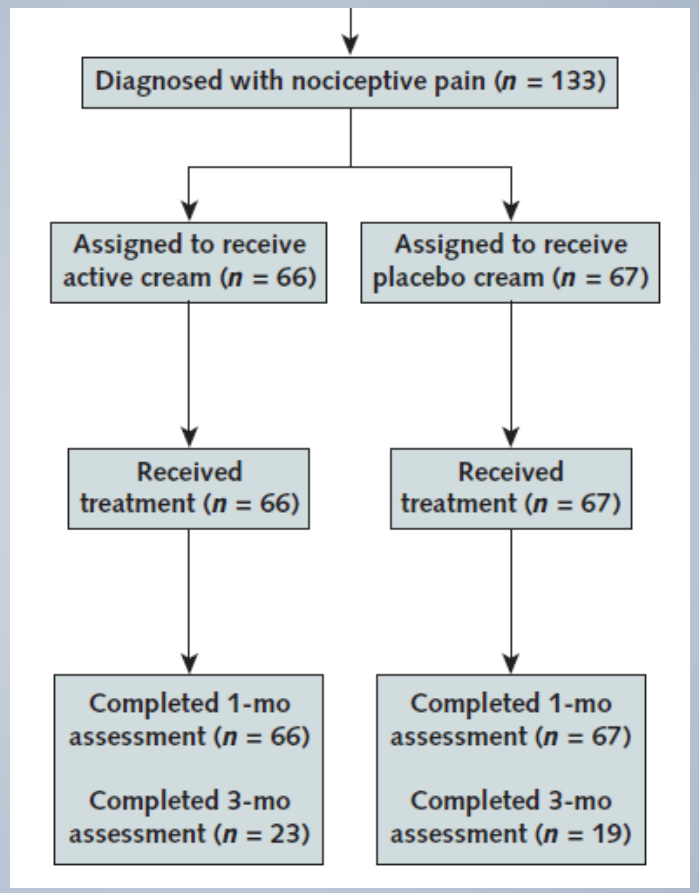
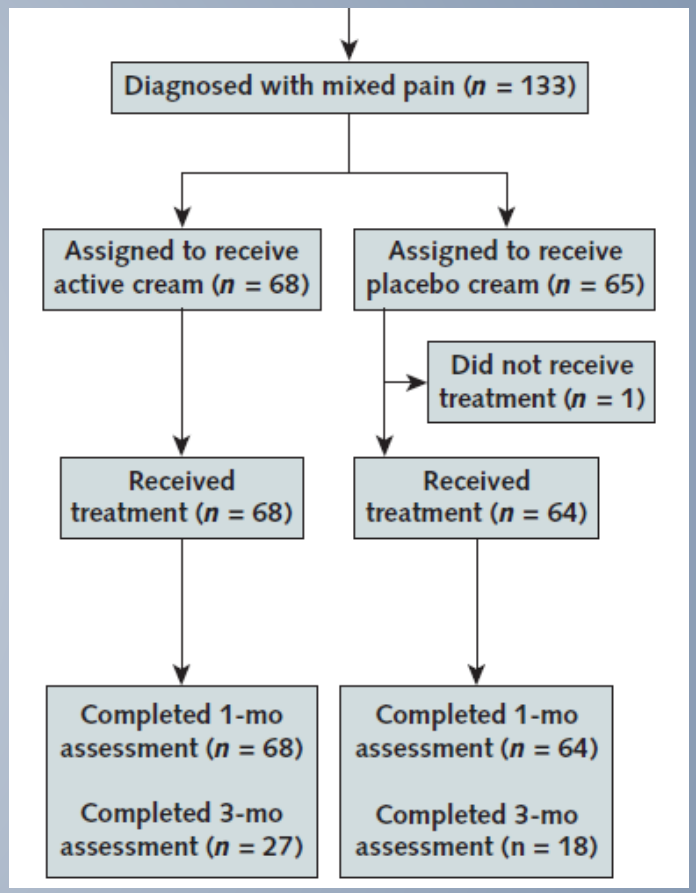
Study Participants and Completion







18+16=34 / 133 = 26%

23+19=42 / 133 = 32%

27+18=45 / 133 = 34%

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Study Outcomes

- **Outcomes**
- Worst pain score and medication reduction at 1 and 3 months
  - No difference between the drug or placebo for any group or pain type
- At 3 months
  - No difference in average pain for any group or pain type
- Four different pain locations
  - No difference in average pain for any group or pain type
- SF-36 Outcomes
  - No difference health or wellbeing scores

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Opinion Questions Posed by NAC

1) Discuss general trends on the use of compounded products
   - compounds v. commercial
2) How often do you use or prescribe compounded topical pain creams?
3) Walk thru process of prescribing/dispensing the compounded product?
4) How are the ingredients selected?
5) List select patient types/situations that dictate topical products
6) Perspective on any patient preferences in regard to compounded pain cream medications (copays, cost, waiting times, access, base (gel, cream, ointment, lotion)
7) Thoughts on safety or effectiveness
8) Dr. Fudin recommendations to committee (if any)…

"Active" Ingredients Used in Lipophilic Cream Base (Transdermal Pain Base [Medisca])

- Neuropathic Pain Arm
  - Ketamine 10%, gabapentin 6%, clonidine 0.2%, and lidocaine 2%
- Nociceptive Pain Arm
  - Ketoprofen 10%, baclofen 2%, cyclobenzaprine 2%, and lidocaine 2%
- Mixed Pain Arm
  - Ketamine 10%, gabapentin 6%, diclofenac 3%, baclofen 2%, cyclobenzaprine 2%, and lidocaine 2%.

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Pharmacology, Practicality, & Pretext

- Baclofen
- Clonidine
- Cyclobenzaprine
- Gabapentin
- Ketamine
- Ketoprofen
- Lidocaine
- Phenytoin

- Compounding Pharmaceutics 101
  - Vehicles and Solubility:
    - ✓ DMSO (dimethylsulfoxide), Aquaphor, Eucerin, Petrolatum, Emulsions, etc.