Integrated Approach to Pain and Opioid Use in Hemodialysis Patients

Manisha Jhamb, MD MPH
Director, Center for Population Health Management
Co-Director Clinical Research
Associate Professor of Medicine
Renal-Electrolyte Division
University of Pittsburgh, PA
Pain in End Stage Kidney Disease (ESKD)

• 50-60% of hemodialysis patients report pain
• Negatively impacts health-related quality of life
• Associated with increased hospitalization & mortality
• Identified as top research priority by patients

Walking hurts, sitting hurts, standing hurts

I have numbness all the time and it’s like an electric shock

I wish there wasn’t so much cramping. That just knocks the stuffing out of you

Opioid Use in Hemodialysis

• United States Renal Data System (2006 – 2010) found:
  – 60% of dialysis patients were prescribed opioids per year
  – 20% had prescriptions for ≥90 days per year
  – Over 1/3rd of the HD patients receive >50 morphine milligram equivalent per day (MME/d)
  – 1 in 5 prescribed opioids that are not recommended or lack safety data in ESKD

• Chronic opioid use in ESKD patients is associated with
  – High risk of fractures and falls
  – Altered mental status
  – Hospitalizations
  – Mortality

Kimmel et al, JASN 2017; Ishida et al, CJASN 2018
Challenges to pain management in ESKD

Provider
- Lack of nephrologist training
- Lack of nephrologist ownership of pain management
- Unfamiliarity with safety, efficacy and dialyzability of medications
- Hesitancy to prescribe opioids

Patient
- Multifactorial etiologies and types of pain
- Altered pain perceptions
- Co-existing psychosocial symptoms
- Fear of addiction to opioids
- Limited non-dialysis time
- Polypharmacy

System
- Care fragmentation
- Lack of quality incentives
- Lack of evidence and guidelines
- Limited access to non-pharm options

Roy, Curr Op Neph HTN, 2020
HOPE Trial
Overall Goal

To evaluate approaches to reducing pain and opioid use among patients with chronic pain who are receiving maintenance hemodialysis for end-stage kidney disease

National Institute of Health (NIDDK)
Consortium Structure

DSMB

NIH HEAL Leadership

Patient Advisors

Single IRB

Scientific and Data Research Center
University of Pennsylvania

Hennepin County

Massachusetts General Hospital

New York University

University of Illinois-Chicago

University of Pittsburgh / Univ of Penn

Univ Wash/ Univ New Mex/ Rogosin

Yale / VA

Vanderbilt / West Virginia University

Slide courtesy: Dr. Laura Dember
Trial Questions

Primary
• Does pain coping skills training over 12 weeks reduce pain interference?

Secondary (Exploratory)
• Is buprenorphine acceptable, well tolerated, and efficacious as an alternative to full agonist opioids for hemodialysis patients taking opioids for pain?
Primary Analysis

Design

- **Phase 1**
  - Week 0
  - Pain Coping Skills Training for 24 Weeks
    - Weeks 0 - 12: Weekly Telehealth Sessions with Coach
    - Weeks 13 - 24: Daily Interactive Voice Response Sessions
  - 50% of Eligible Patients

- **Phase 2**
  - Week 24
  - Group A: Not Offered Buprenorphine
  - Group B: Switched to Buprenorphine
  - Group C: Declined Buprenorphine
  - Group D: Not Offered Buprenorphine
  - Group E: Switched to Buprenorphine
  - Group F: Declined Buprenorphine

- **Usual Care for 24 Weeks**
  - 50% of Eligible Patients

**Slide courtesy: Dr. Laura Dember**
Pain Coping Skills Training

Baseline

Weekly Telehealth Sessions

Week 12

Daily Assessment Calls

Week 24

Pain Coping Skills Training Telehealth Sessions
(Cognitive Behavioral Therapy + Motivational Interviewing)
Weekly 45 minute sessions
Telehealth 1 on 1 with live coach

Interactive Voice Response (IVR) Booster Sessions
(Touchtone phone and voice messages with coach)
Customized Messages +
Asynchronous Weekly Coach Feedback +
Self-Paced Skill Review

Slide courtesy: Dr. Laura Dember
Buprenorphine Intervention (Week 24 – 36)

- Partial opioid agonist, similar analgesic properties to full agonists but safer due to less respiratory depression, lower risk of overdose
- In hemodialysis setting, safety is established and no need to modify the dose
- Use in HOPE is limited to those who remain on opioids (≥20 MME/day) after Phase 1 intervention (PCST or Usual Care)
- Drug is shipped from central pharmacy to participant’s home
Unique Aspects of HOPE Trial

- Multidisciplinary – Nephrology, Pain, Opioid and Addiction Medicine, Behavioral Therapy experts

- Using telemedicine during dialysis – overcoming barriers of access, transportation, time

- Diverse racial and geographic participant representation
Patient Advisors

• Development of the trial design, interventions, and protocol
• Drafting of the informed consent documents
• Creation of multiple recruitment materials including a video
• Development of content for the Pain Coping Skills intervention
• Participation in HOPE Committees for:
  – Recruitment Committee
  – Publications Committee
  – Patient Advisory Committee
  – Executive Committee
• Representation on the HEAL Community Partner Committee
Overall

- Targeted
- Actual
- Projected

Total target = 640 participants;
Randomized = 304 (47.5% of total target; 94.3% of today's target);

Based on the rate of recruitment in the last 30 days (5.1 patients/week),
the recruitment would end on 2023-06-22
Intervention to Reduce Stigma - Ancillary study

Goal: Create a multi-level intervention to reduce stigma for buprenorphine use for individuals with End Stage Kidney Disease and Chronic Pain

- Qualitative Individual Interviews
  - **Professional Workforce**
    - Physicians
    - Dialysis Organizations
    - Insurers
    - Pharmacists
  - **ESKD Patients**

- Design Sprint
  - Fast-paced, team-based human design method
  - 3 sprints: October 2021, January 2022, March 2022

- Survey
  - Internalized Stigma in Chronic Pain Scale for all HOPE participants