Buprenorphine Treatment in the Primary Care Setting: Cases and Clinical Issues

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Disclosures

- None
Buprenorphine History

- Synthesized in 1969—derived from thebaine
- First marketed for pain in the early 1970s
- Available in a variety of strengths and dosage forms; with and without naloxone
Buprenorphine History

- Also available in transdermal patch (Butrans) and buccal (Belbuca)--not approved for addiction
- In 2010, of 23,000 doctors with waiver only about half had ever written a prescription.
- 20% treat fewer than 3 patients and < 10% treat more than 75
A side note on pain

Commentary

The clinical analgesic efficacy of buprenorphine

R. B. Raffa* PhD, M. Haidery* PharmD, H.-M. Huang* PharmD, K. Kalladeen* PharmD, D. E. Lockstein* PharmD, H. Ono* PharmD, M. J. Shope* PharmD, O. A. Sowunmi* PharmD, J. K. Tran* PharmD and J. V. Pergolizzi†‡§ Jr MD

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Fig. 2. The analgesic efficacy of s.l. buprenorphine (0.4 mg) was compared with that of i.m. morphine (10 mg) in a randomized, double-blind study of post-op pain of 101 patients (mean age: 40–45 years). Pain was measured using a 10-cm pain scale (0 = none, 10 = as much as imaginable). Buprenorphine produced the same pain relief as did morphine during the first 2 h and modestly greater pain relief from 2 to 6 h. Redrawn from Edge et al."

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*Note: The text is a commentary on the clinical efficacy of buprenorphine, a medication used for pain management. The text includes a figure illustrating the comparison of pain relief between buprenorphine (s.l.) and morphine (i.m.) in a post-operative setting.
But isn’t buprenorphine a partial agonist?
Take-home point about pain

There is no compelling evidence that there is a ceiling effect for analgesia, though there is lots of clinical lore

There is a ceiling effect for respiratory depression

Kappa antagonism may help with opioid induced hyperalgesia
You’ve all heard about the twin epidemics of opioid addiction and overdose.
Opioid use disorder is *endemic* in Baltimore: it persists and is transmitted across generations and sociodemographic groups.

Maryland localities outside of Baltimore are struggling as well.
Table 6. Number of Opioid-Related Intoxication Deaths\(^{1,2}\) by Place of Occurrence, Maryland, 2007-2016 and YTD 2017 Through September.\(^3\)

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\(^1\)Includes deaths that were the result of recent ingestion or exposure to prescription and illicit opioids.

\(^2\)Includes only deaths for which the manner of death was classified as accidental or undetermined.

\(^3\)Counts for 2017 are not complete.
Figure 2. Number of Opioid-Related Deaths Occurring in Maryland from January through September of Each Year.*
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^1Includes deaths that were the result of recent ingestion or exposure to prescription or illicit fentanyl.

^2Includes only deaths for which the manner of death was classified as accidental or undetermined.

^3Counts for 2017 are not complete.
Figure 4. Number of Fentanyl-Related Deaths Occurring in Maryland from January through September of Each Year.*
Diagnosis of OUD (DSM5)

Opioid Use Disorder
Diagnostic Criteria

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
Diagnosis of OUD (DSM5)

7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.

8. Recurrent opioid use in situations in which it is physically hazardous.

9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.

10. Tolerance, as defined by either of the following:
   a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
   b. A markedly diminished effect with continued use of the same amount of an opioid.

   **Note:** This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

11. Withdrawal, as manifested by either of the following:
   a. The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal).
   b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.
Diagnosis of OUD (B-more)

- “I’m Tired”
Levels of Care

- White-knuckling/cold turkey
- Self-help/12-step
- Pharmacotherapy--OBOT vs OTPs
- Outpatient and Intensive Outpatient
- Day Hospitalization
- Residential Treatment
- Supportive housing (often coupled with OP, IOP, or day hospitalization)
Special Rules on Confidentiality

- 42 CFR Part 2 supersedes HIPAA
- Need written release to disclose participation in drug/alcohol treatment
- A program is covered by “Part 2” if there are “medical personnel or other staff...whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers.” (42 CFR § 2.11 (b), (c))
How to treat OUD with buprenorphine/naloxone

• Start
• Stabilize
  • Regular visits and monitoring
  • Appropriate level of care
• Continue
  • Regular visits and monitoring
  • Appropriate level of care
Cases
Case 1: Mike

48 year old M, HIV & HCV Ab positive. On HAART.
CC: “I’m tired.”
HPI: Intranasal heroin for 20 years. Past tx--two month-long stays in residential treatment (Gaudenzia and Tuerk House). On methadone for three weeks in 2010--didn’t like having to go every day. Using 2-3 pills/day. Also smokes one blunt daily and ½ PPD Newports. Denies alcohol and other illicit drug use.
Case 1: Mike

Rapid urine toxicology: +fentanyl, +buprenorphine, +benzodiazepines, +THC

CMP: AST 75, ALT 85 (lab ULN 40)

No objective signs of withdrawal

Thoughts?
Case 1: Mike

“Oh yeah, I took like a tiny piece of a bute on Wednesday”

“I’m starting to feel sluggish.”

“Benzos? I don’t take pills. It must be in the scramble!”
Case 1: Mike

How to start?
MACS
1-855-337-6227 (MACS)
Maryland Addictions Consultation Service

Components:

- Phone Consultation Service via telephone “Warm Line”
  - Clinical questions, resources, and general referral information
- Continuing Education
  - Training opportunities related to Opioid Use Disorders
- Resource & Referral Networking
  - Assistance identifying addiction and behavioral health resources that meet the needs of your patients
What type of questions are appropriate?

- Initiation and maintenance of buprenorphine
- Diagnostic questions
- Screening tools
- Psychopharmacology
- Alternative medication treatments
- Comorbid diagnoses
- Community resources and referrals
Case 1: Mike

“Oh yeah, I took like a tiny piece of a bute on Wednesday”

“I’m starting to feel sluggish.”

“Benzos? I don’t take pills. It must be in the scramble!”
Case 1: Mike

How to start?
Before doing the buprenorphine/naloxone part:
• a clinic-specific treatment agreement
• appropriate level of psychosocial care (per clinic policy and clinical assessment--cf. ASAM Criteria)
• establish expectations regarding other drugs of abuse, including alcohol
• Check the PDMP
Case 1: Mike

How to start?

*Insurance note: Maryland MA will pay for 2 films/tablets per day of any dosage strength*
Case 1: Mike

*Home induction:*

Most important instruction: **WAIT UNTIL YOU ARE REALLY FEELING A LOT OF WITHDRAWAL**

Then take 2 to 4mg (or equiv.) of the medication under your tongue.

Wait an hour. If you are still feeling sick, you may take another dose.
Case 1: Mike

Home induction:
Consensus is that a patient may take up to 8 to 12 mg of buprenorphine the first day, in divided doses. Remember that medications take 4-5 half-lives to reach steady state. Buprenorphine has a >24hr half-life.
This means that even on the same daily dose, the patient will feel better and better over the first few days.
Case 1: Mike

*Home induction:*
Some patients do well on lower doses. I have many patients who are stable on doses between 2 and 12 mg per day. It is not usually appropriate (or necessary) to prescribe 16mg daily starting on day 1.
Case 1: Mike

*Home induction:*
Have a follow up visit one week after initial visit
Case 1: Mike

*Home induction:*

Possible wrinkle: Mike calls 4 days after his initial visit and says “I’ve been taking 3 strips a day and I’m all out of medication.”
Case 1: Mike

Home induction:
How long an rx at a time?
Case 1: Mike

*Home induction:*
How long an rx at a time?
Frequency of urine monitoring?
Case 1: Mike

Home induction:
How long an rx at a time?
Frequency of urine monitoring?
Type of urine monitoring?
Case 2: Lili

Lili is a 31 year old F who presented for treatment of opioid use disorder, specifically addiction to prescription oxycodone, which she was initially prescribed for her “exploded disc.”
Case 2: Lili

After 2 months, Lili is able to remain abstinent from oxycodone on 16mg/day of buprenorphine/naloxone. At treatment initiation she agreed to attend weekly appointments with her addiction counselor.

However, she is persistently positive for THC and cocaine on her urine toxicology.
Case 2: Lili

When you point this out, Lili says “so you’re going to detox me?”
Case 2: Lili

- Assess patient goals--the collaborative spirit of MI
- Review level of care
- Remember contingency management (esp. as reflected in frequency of visits)
- Check the PDMP
Case 3: Rhonda

Rhonda (age 60) came in to start buprenorphine for her heroin addiction. She is stabilized at 12mg/day for the first three months, and she sees her addiction counselor weekly.

Initial urine toxicology was similar to Mike’s, and then was positive for buprenorphine only.

Recently, Rhonda’s urine has been positive for benzodiazepines the last two checks. She has been consistently negative for opioids.
Case 3: Rhonda

Next steps?
Case 3: Rhonda

Next steps?
- PDMP
- Frequency of monitoring
- Call-backs
- Level of care
- CDC letter
1-855-337-6227 (MACS)
Conclusions

Buprenorphine is safe.
It is very satisfying to be able to treat a deadly condition quickly and effectively.
MACS can help you when you get stuck.
Thank you

Email: agreenbl@som.umaryland.edu

Please fill out evaluation emailed to you!