AETC AIDS Education & Training Center Program Mountain West

Advanced Topics In Buprenorphine Care: “Microdosing” and XR subcutaneous buprenorphine

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Last Updated:

Disclosures

No conflicts of interest or relationships to disclose

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OUTLINE

- Buprenorphine Prescribing: Update on regulatory changes
- “Microdosing”
  - Buprenorphine pharmacology
  - The trouble with standard induction
  - Sample approach to microinductions
- XR Subcutaneous Buprenorphine
  - Controlled trials and real world evidence
  - Dosing and serum levels
  - A word on logistics: Coverage, storage, administration

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Buprenorphine Prescribing Regulatory Updated

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New HHS guidance (4/27/2021)

- 8 hour training no longer required to apply for initial X-waiver to prescribe buprenorphine.
- **IMPORTANT: Must still register with the DEA!!!**
  - **https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php**
- Training is still required to prescribe >30 concurrent patients

More information at: https://www.samhsa.gov/medication-assisted-treatment/practitioner-resources/faqs

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“Microdosing” (aka low-dose buprenorphine initiation)

Disclaimer

- “Microdosing” is not an FDA approved use of buprenorphine/naloxone.
- Literature is thus far limited to case reports , case series and a single larger retrospective cohort study, and there is no evidence-based protocol. There is, however, accumulating clinical experience and RCTs in the works.

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Properties of Buprenorphine

Partial agonist at mu receptor

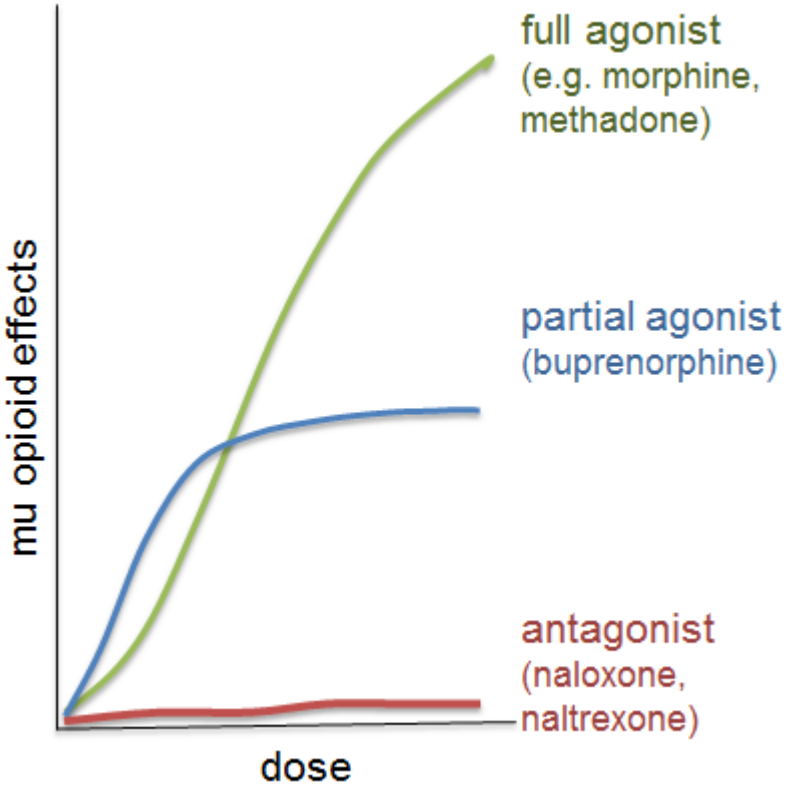
- Comparatively minimal respiratory suppression and no respiratory arrest when used as prescribed

High affinity for mu receptor

- Blocks other opioids

Slow dissociation from mu receptor

- Stays on receptor for a long time ~ 24-36 Hours



Adapted from PCSS Buprenorphine waiver training

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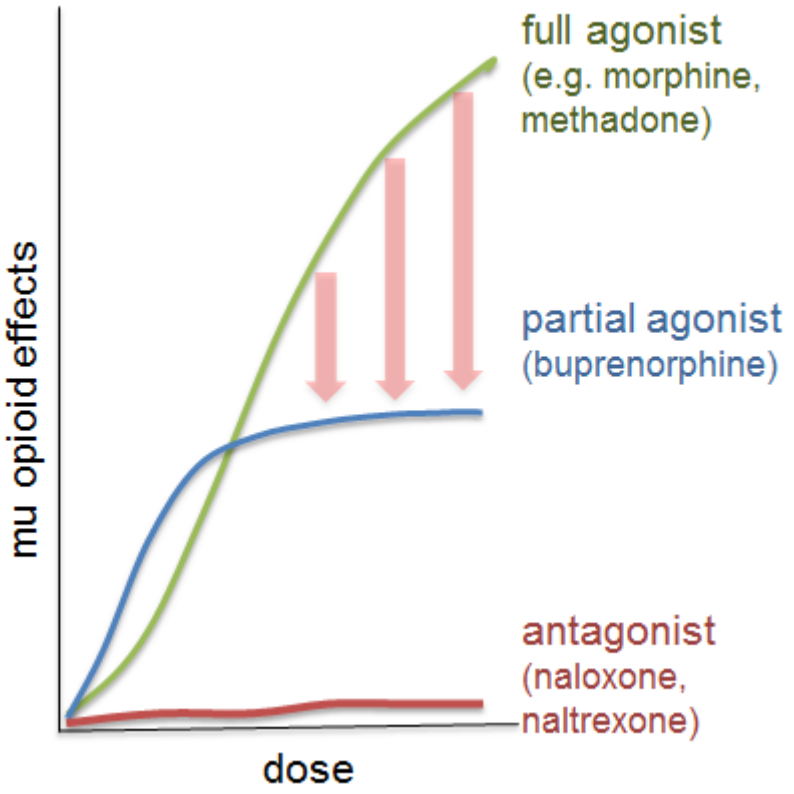
Properties of Buprenorphine

These unique properties make buprenorphine effective at:

- Treating opioid withdrawal
- Minimizing craving
- Blocking reinforcing effects of other opioids
- Not inducing respiratory depression

They also make **initiation** challenging due to the risk of PRECIPATED WITHDRAWAL



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Traditional Buprenorphine Induction

- For short-acting opioids (including heroin), wait >12 hours after last dose, until in moderate withdrawal.
- Take 2-4mg SL as first dose. May repeat 2 hours later and up-titrate (generally to 16mg total daily dose)
- Generally works very well with in-office or home induction (aka “self starts”).

Problems with traditional induction

- Patients on methadone
- Patients with acute or chronic pain
- Patients using fentanyl
- Patients who've had trouble with the standard induction

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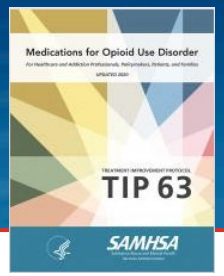
Patients on methadone



- Standard inductions more difficult. Patients generally taper to 30 mg to 40 mg methadone per day and remain on that dose for at least 1 week before starting buprenorphine.
- **Patients tapering from higher doses can face significant risks of return to use during this tapering process.**
- Need to wait 24-48 hours before initiating low doses of buprenorphine.
- “The lower the methadone dose and the longer it’s been since the last dose, the easier the transition.”

Patients with pain

- Patients on chronic opioid therapy may not have as much experience self-managing withdrawal as patients with OUD. The withdrawal necessary in a standard induction may present a substantial barrier to a patient's willingness to rotate to buprenorphine.
- Hospitalized patients with OUD with an acute pain condition may not be able to forgo opioid analgesia long-enough for a standard induction.

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Non-prescribed fentanyl

- Though prior pharmacokinetic studies of fentanyl report half lives ranging from 1.5-7 hours, these studies generally relied on brief periods of drug administration.
- Fentanyl is highly lipophilic, allowing it to be sequestered in adipocytes in chronic users, similar to THC.

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" I was almost 72 hours into withdrawal --- and I took it [buprenorphine] and it made me . . . I couldn't believe it. Cuz I don't puke or get diarrhea, I don't have that happen ever . . . But immediately – Bam! Not even five minutes after I took it I was dripping with sweat. It felt like water had just gotten dumped all over me, I'm puking and it's coming out every end."

"[Buprenorphine] sends me into precipitated withdrawals every f**** time that I try to get off of fentanyl. Then I have these Sub doctors telling me that it's not real and it's like, go f**** ask the people that are buying it off the streets. It is real! I waited 80 hours. I was in a dotx and after 80 hours they gave me a Suboxone and it still put me into precipitated."

Silverstein et al. Int Journal of Drug Policy, 2019

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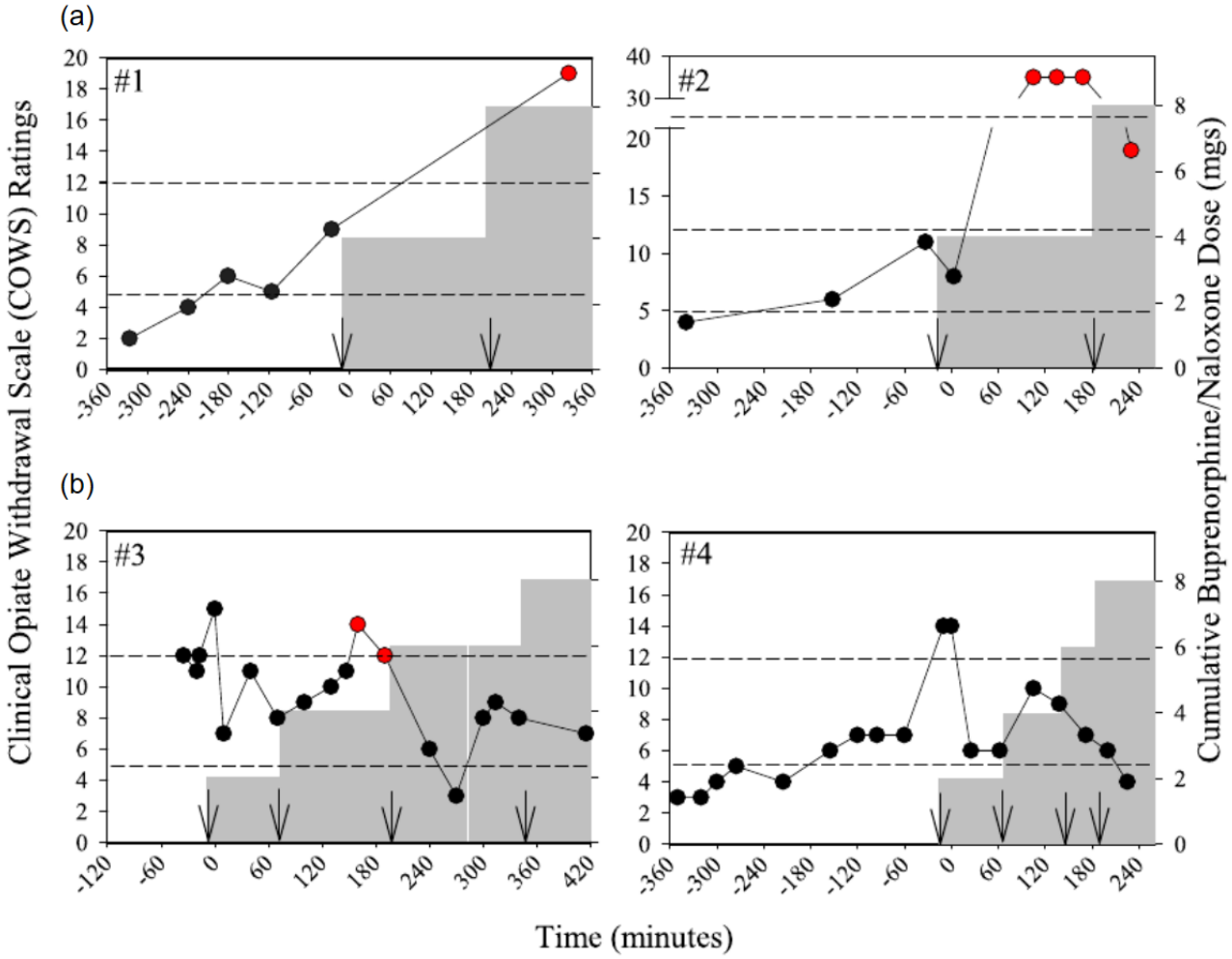

Antoine, D et al. The American Journal on Addictions, 2020

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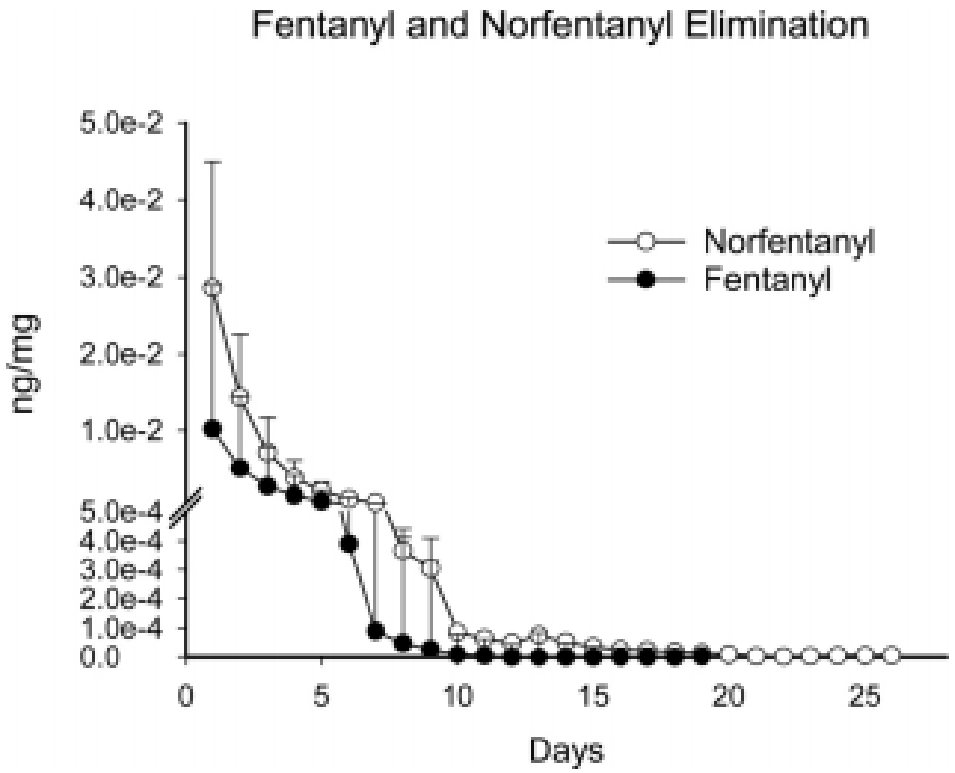

Mean time for fentanyl clearance: 7.3 days
Meant time for norfentanyl clearance: 13.3 days

Huhn et al, Drug Alcohol Depend, 2020

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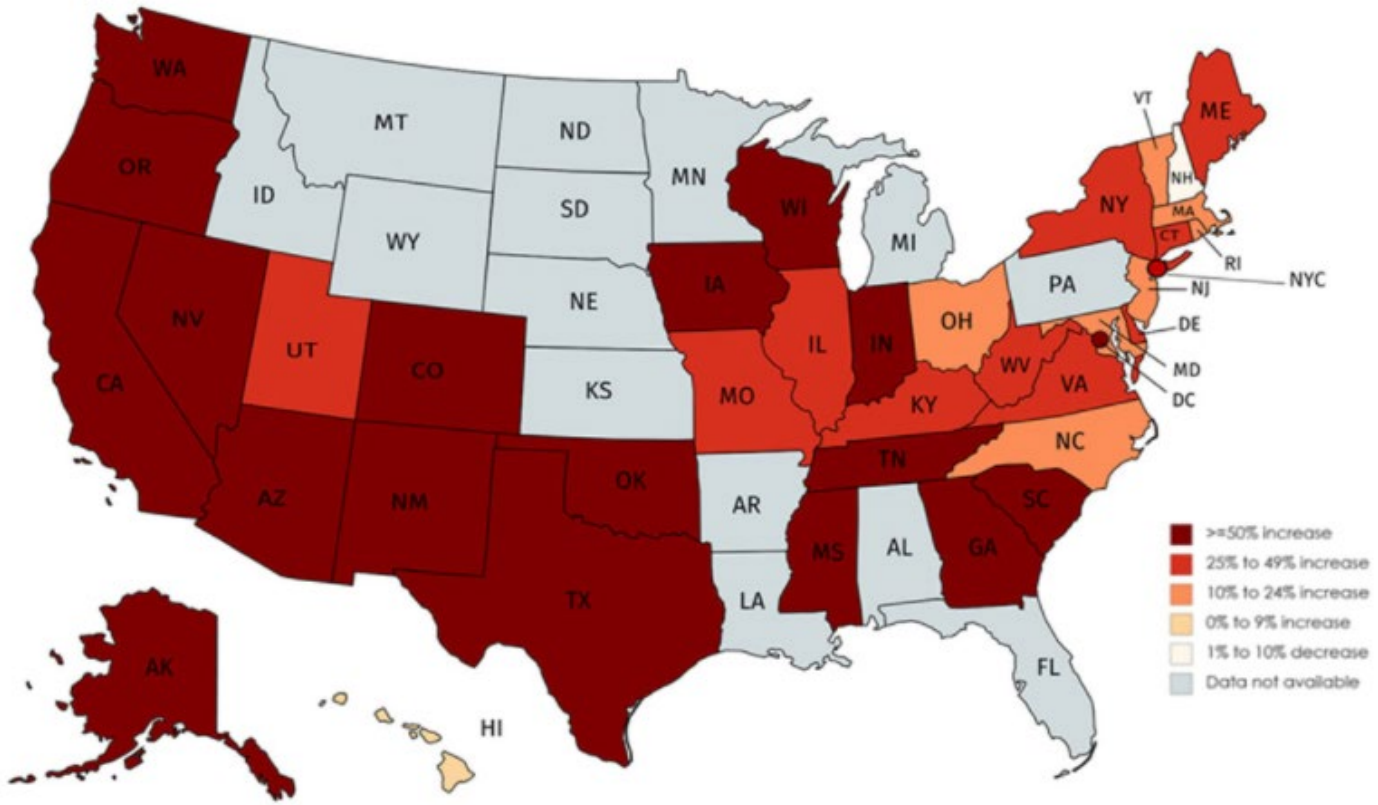
Fentanyl overdoses increasing

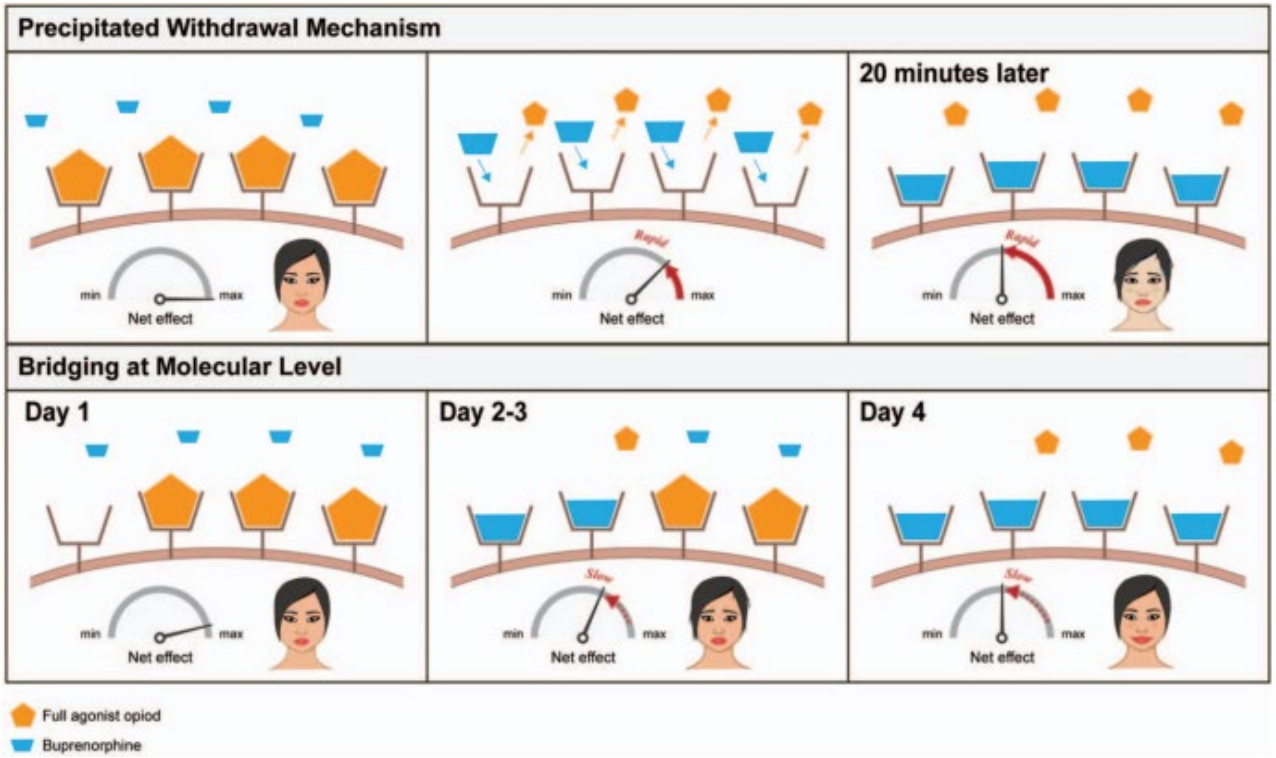
Figure 3: Percentage change in 12-months ending provisional[a] count of fatal overdoses involving synthetic opioids[b], 36 states, the District of Columbia, and New York City[c]: Deaths from 12-months ending in June 2019 to 12-months ending in May 2020[d]



[HAN Archive - 00438 | Health Alert Network (HAN) (cdc.gov)]

Idea behind “microdosing”

Use ultra low doses to ease buprenorphine onto the receptor while continuing full agonists, to avoid the “wash-out” period of withdrawal



Ghosh et al. The Canadian Journal of Addiction, 2019

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The Bernese Method

Substance Abuse and Rehabilitation
Dovepress
open access to scientific and medical research
Open Access Full Text Article
CASE SERIES

Use of microdoses for induction of buprenorphine treatment with overlapping full opioid agonist use: the Bernese method

Table 1 Buprenorphine dosing and use of street heroin in case 1

Day	Buprenorphine (sl)	Street heroin (sniffed)
1	0.2 mg	2.5 g
2	0.2 mg	2 g
3	0.8+2 mg	0.5 g
4	2+2.5 mg	1.5 g
5	2.5+2.5 mg	0.5 g
6	2.5+4 mg	0
7	4+4 mg	0
8	4+4 mg	0
9	8+4 mg	0

Abbreviation: sl, sublingual.

Hämmig et al. *Subst Abuse Rehabilitation. 2016*

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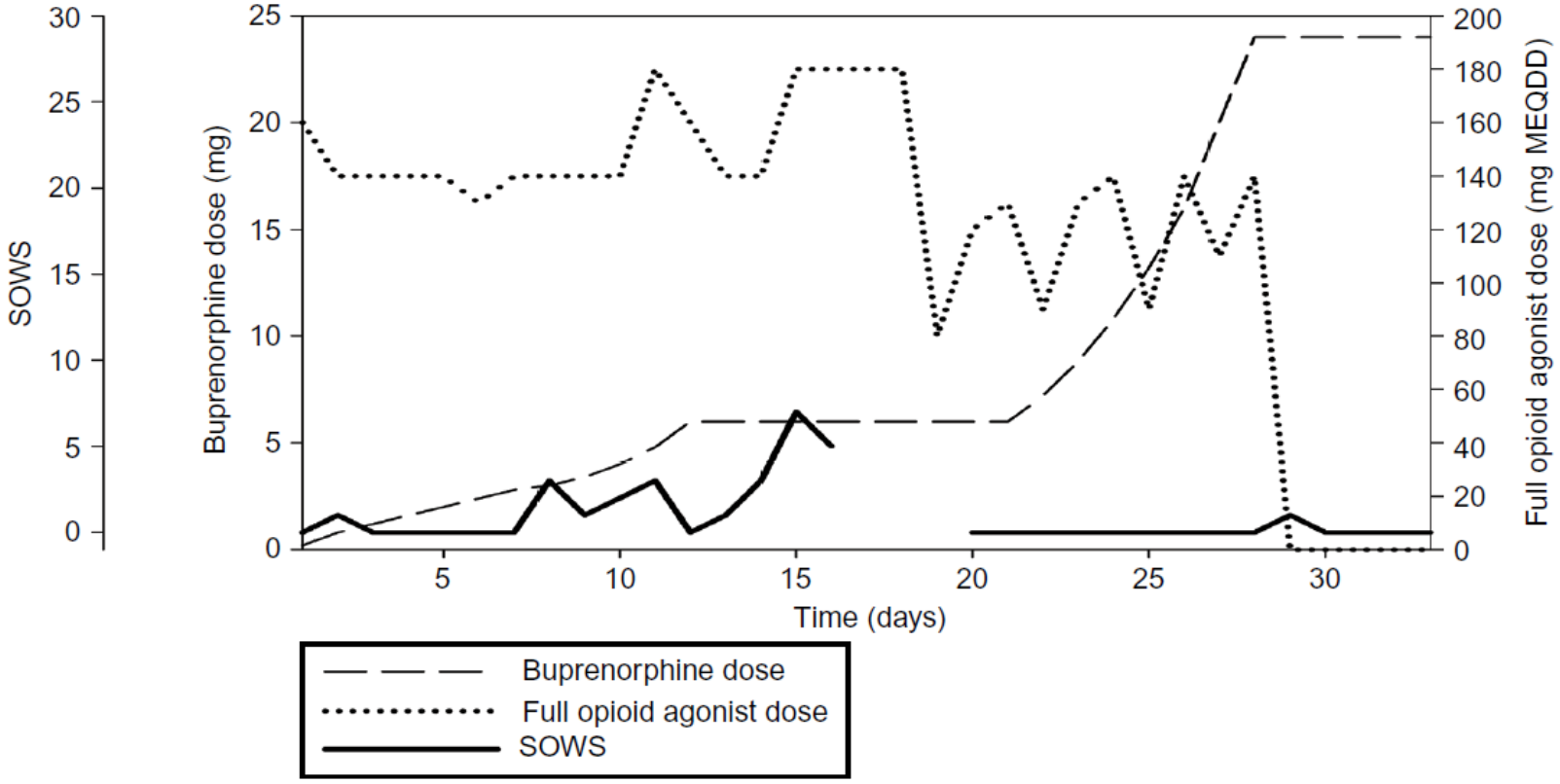

Figure 1 Daily buprenorphine dose (mg), full agonist dose (in MEQDD), and SOWS scores of case 2.
Abbreviations: MEQDD, methadone equivalent daily dose; SOWS, short opioid withdrawal scale.

Hämmig et al. *Subst Abuse Rehabilitation. 2016*

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What's the evidence?

- Systematic Review found case reports and small case series totaling 63 patient experiences in 20 publications.
- In ambulatory and hospital settings
- A variety of approaches
  - Transitioned from a variety of opioids over a range of different doses without significant withdrawal.
  - Initial doses ranged most frequently from 0.2-0.5mg
  - Various schedules, most over a period of 4-8 days and most completed the cross-titration at 8-16mg of bup.

Ahmed et al, American Journal on Addictions, 2020

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OHSU retrospective cohort study

- Mean prescribed MME prior to bup was 198
- Mean duration was 6 days.
- Of the 13 who discontinued
  - 1 transferred to comfort care.
  - One attribute SEs to bup
  - 5 had fear of inadequate pain control
  - 2 requested methadone

TABLE 2. Characteristics of Low-dose Buprenorphine Initiations

Induction Characteristic	n (%)
Unique low-dose initiation	72
Reason for low-dose initiation[*]	
Co-occurring pain	66 (91.7)
Anxiety around thought of withdrawal	50 (69.4)
Transition from high dose methadone	21 (29.2)
History of precipitated withdrawal	7 (9.7)
Opioid withdrawal intolerance	5 (6.9)
Other	13 (18.1)
Days of low-dose initiation in hospital – mean (SD)	6 (2.7)
Low-dose initiation completion status	
Completed in hospital	50 (69.4)
Scheduled to complete as outpatient	9 (12.5)
Discontinued in hospital[†]	13 (18.1)
Premature discharge during low-dose initiation	2 (2.8)

[*]Not mutually exclusive.

†One individual did not complete two low-dose initiations before the third, completed low-dose initiation.

Button, et al. J Addict Med. 2021

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Approach to the patient

- These dosing regimens are complicated. Patients must be motivated and organized to accomplish this successfully as an outpatient.
- For patients wishing to transition from methadone, important to have risk/benefit discussion of transition which includes OTP providers. OTP may be able to provide structured transition. More likelihood of success at doses below 80mg.
- Provide plenty of supports (regular visits and/or phone check-ins, can pharmacy provide blister packs, observed dosing through an OTP?).

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Example schedule: 1 week

Example use: Patients with prior failed induction, patients with long-term chronic fentanyl use, patients with withdrawal anxiety/intolerance.

Day	Actual Dose/Day	Fraction of Buprenorphine-Naloxone Film	Opioid
Day 1	0.5mg once	1/4 film (2/0.5mg) once	Continue current dose
Day 2	0.5mg BID	1/4 film (2/0.5mg) BID	Continue current dose
Day 3	1mg BID	1/2 film (2/0.5mg) BID	Continue current dose
Day 4	2mg BID	1 film (2/0.5mg) BID	Continue current dose
Day 5	4mg BID	2 films (2/0.5mg) BID	Continue current dose
Day 6	8mg daily	1 film (8/2mg) once	Continue current dose
Day 7	8mg in AM, 4mg in PM	1 film (8/2mg) in AM ½ film (8/2mg) in PM	STOP opioid
Ongoing	8mg BID	1 film (8/2mg) BID	

- **Adapted from Marwah, et al. *Can Fam Physician*, 2020. Terasaki, et al Pharmacotherapy 2019**

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Example schedules: 2 week (e.g. patient transitioning from methadone)

Day	Actual Dose/Day	Fraction of Buprenorphine-Naloxone Film	Methadone Dose
Day 1	0.5mg	0.25 film (2/0.5mg)	Continue current dose
Day 2	0.5mg	0.25 film (2/0.5mg)	Continue current dose
Day 3	1mg	0.5 film (2/0.5mg)	Continue current dose
Day 4	1.5mg	0.75 film (2/0.5mg)	Continue current dose
Day 5	2mg	1 film (2/0.5mg)	Continue current dose
Day 6	3mg	1.5 films (2/0.5mg)	Continue current dose
Day 7	4mg	2 films (2/0.5mg)	Continue current dose
PROVIDER CHECK-IN			
Day 8	5mg	2.5 films (2/0.5mg)	Continue or taper, per patient preference
Day 9	6mg	3 films (2/0.5mg)	
Day 10	7mg	3.5 films (2/0.5mg)	
Day 11	8mg	1 film (8/2mg)	
Day 12	10mg	1.25 films (8/2mg)	
Day 13	12mg	1.5 films (8/2mg)	Stop Methadone
Day 14	16mg	2 films (8/2mg)	

- Adapted from Marwah, et al. *Can Fam Physician*, 2020.

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Transdermal patch approach

- For patients rotating for chronic pain, it is possible to use a butrans patch for the initial doses of buprenorphine. Cost and DEA regulations make this approach more complicated in the outpatient setting.

TABLE 4. Low-Dose Buprenorphine Initiation Protocol

A. Standard Protocol

Initiation Day	Dosing Schedule	Notes
1	20 mcg buprenorphine transdermal patch × 24 hours	Patch on × 7 days
2	patch + 1 mg SL bup/nx twice daily	
3	patch + 2 mg SL bup/nx twice daily	
4	patch + 4 mg SL bup/nx twice daily	
5	patch + 6 mg SL bup/nx twice daily	
6	patch + 8 mg SL bup/nx twice daily	
7	increase bup/nx as needed NTE 24 mg/24 hours*	Remove patch

B. Acute pain protocol

Initiation Day	Dosing Schedule	Notes
1	20 mcg buprenorphine transdermal patch × 24 hours	Patch on × 7 days
2	patch + 1 mg SL bup/nx twice daily	
3	patch + 1 mg SL bup/nx three times daily	
4	patch + 2 mg SL bup/nx three times daily	
5	patch + 4 mg SL bup/nx three times daily	Begin full opioid agonist taper‡
6	increase bup/nx as needed for pain NTE 24 mg/24 hours†	
7		Remove patch

C. Transition from Methadone protocol

Initiation Day	Dosing Schedule	Notes
1	20 mcg buprenorphine transdermal patch × 24 hours	Patch on × 7 days; Continue methadone§
2	20 mcg buprenorphine transdermal patch × 24 hours	No SL bup/nx; Continue methadone
3	patch + 1 mg SL bup/nx × 1 dose	Continue methadone vs. start methadone taper based on patient preference¶
4	patch + 1 mg SL bup/nx twice daily	
5	patch + 2 mg SL bup/nx twice daily	
6	patch + 3 mg SL bup/nx twice daily	
7	4 mg SL bup/nx twice daily	Remove patch
8	5 mg SL bup/nx twice daily	
9	6 mg SL bup/nx twice daily	
10	8 mg SL bup/nx twice daily	Stop methadone
11	increase bup/nx as needed NTE 24 mg/24 hours*	

Button, et al. J Addict Med. 2021

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Troubleshooting

- If one dose is missed during induction, consider repeating the previous day's dose and continue the schedule. If two doses are missed, consider restarting.
- Not generally necessary, but symptomatic management for withdrawal symptom can also be offered (clonidine/tizanidine, loperamide, NSAIDs, hydroxyzine).

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Take home points

- Buprenorphine initiation without withdrawal “wash-out” period is possible.
- May be an option for patients who are transitioning from methadone, patients with acute or chronic pain, or patients who have failed prior inductions or chronically use non-prescribed fentanyl.
- There is no evidence-based protocol – plans should be flexible and individualized
- Dosing regimens can be very complicated and patients need to have a lot of support to be successful.

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XR Subcutaneous Buprenorphine

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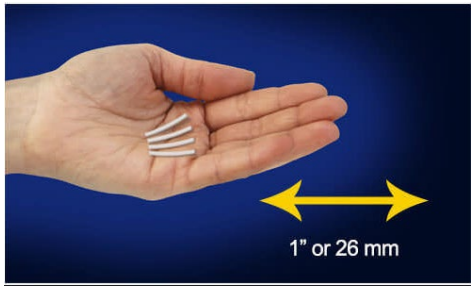
Sublocade: FDA approved 2017

Brixadi: Not yet commercially available.



Probuphine: Low uptake. Sales discontinued in 2020

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Potential Uses?

- Patients transitioning from ED?
  - NIDA clinical trial underway
- Patients leaving the criminal justice system
  - Clinical trial underway
- Patients with adherence issues to SL formulation
- Patients with access issues (for visits/urine monitoring)
- Patients with issues storing bup safely and securing it from theft.
- Patients requiring less inter-dose fluctuations in plasma concentration.

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Sublocade®

- One-month long SQ depot injection, immediately turns into a solid, no special training required, RN can administer
- Two dose schemes: 300 mg (1.5 mL) and 100 mg (0.5 mL)
  - FDA label: 300 mg loading for first two months, followed by maintenance period of monthly 100 mg maintenance
- Patient must be maintained on SL Bup > 8mg, for > 7 days prior to injection
- Sub-cutaneous injection to abdomen only, can be painful, pre-medication with local lidocaine may help.
- Must be stored refrigerated and highly secure as diversion and IV use could result in thromboembolic events.

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Evidence of Efficacy

Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial

Barbara R Haight, Susan M Learned, Celine M Laffont, Paul J Fudala, Yue Zhao, Amanda S Garofalo, Mark K Greenwald, Vijay R Nadipelli, Walter Ling, Christian Heidbreder, for the RB-US-13-0001 Study Investigators*

- Just over 500 adults with mod-severe OUD, excluding pregnant patients and those with other substance use disorders.
- 4:4:1 randomization to
  - 300mg monthly for 6 months
  - 300mg monthly x2 months, then 100mg monthly
  - Placebo injections
- Primary Outcome: % abstinence from opioids (UDS and self-report).

Haight, et al. Lancet 2019

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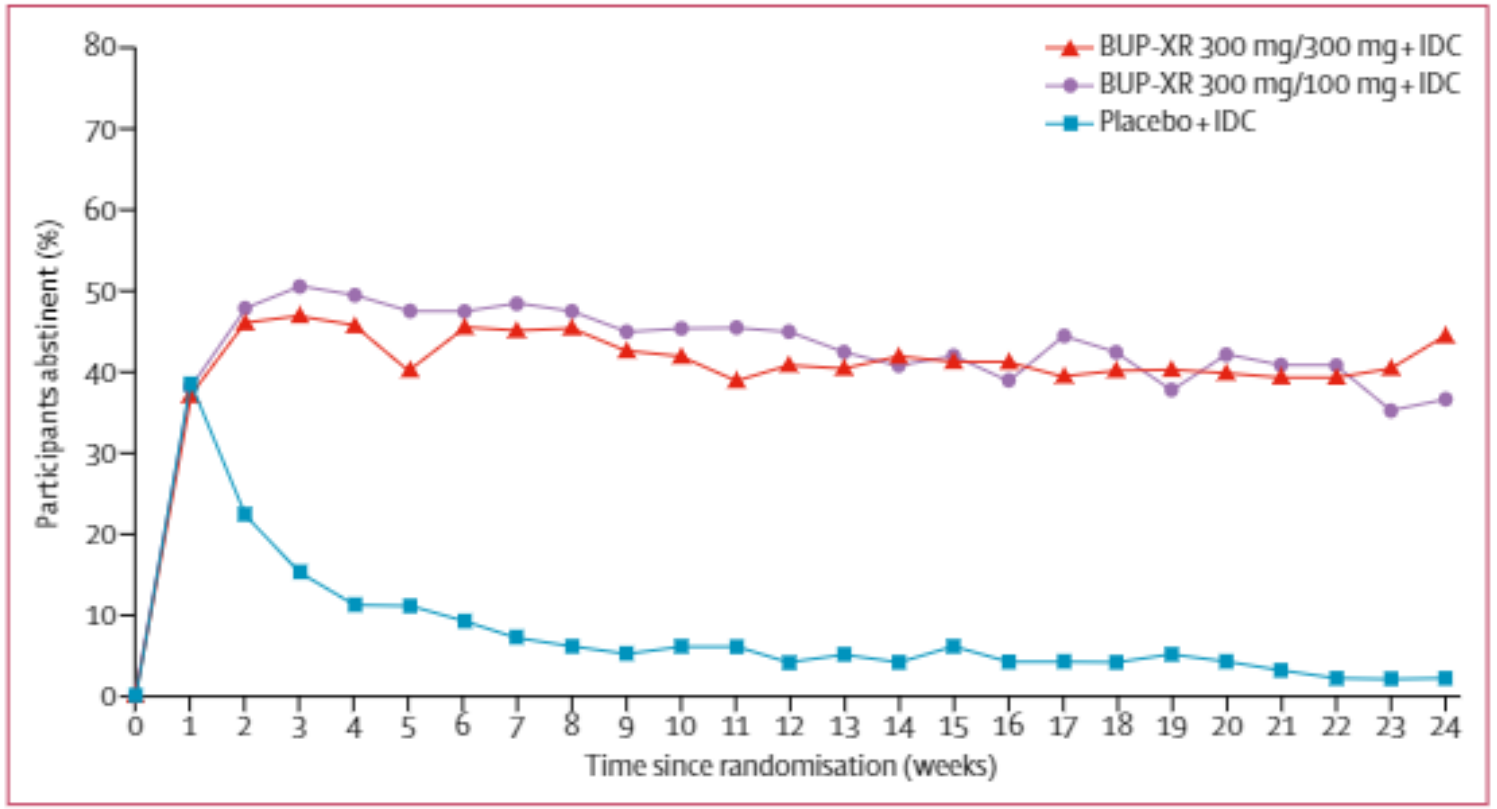

Haight, et al. Lancet 2019

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Safety

	BUP-XR 300/300 mg plus individual drug counselling (n=201) (n=201)	BUP-XR 300/100 mg plus individual drug counselling (n=203) (n=203)	Placebo plus individual drug counselling (n=100)
Any treatment-emergent adverse event	134 (67%)	155 (76%)	56 (56%)
Any serious treatment-emergent adverse event	7 (3%)	4 (2%)	5 (5%)
Any severe treatment-emergent adverse event	13 (6%)	15 (7%)	4 (4%)
Any treatment-emergent adverse event leading to discontinuation	10 (5%)	7 (3%)	2 (2%)
Any treatment-emergent adverse event leading to death	1 (<1%)	0	0
Treatment-emergent adverse events, by preferred term*			
Headache	17 (8%)	19 (9%)	6 (6%)
Constipation	16 (8%)	19 (9%)	0
Nausea	16 (8%)	18 (9%)	5 (5%)
Injection-site pruritus	19 (9%)	13 (6%)	4 (4%)
Vomiting	11 (5%)	19 (9%)	4 (4%)
Insomnia	17 (8%)	13 (6%)	11 (11%)
Upper respiratory tract infection	12 (6%)	15 (7%)	1 (1%)
Injection-site pain	12 (6%)	10 (5%)	3 (3%)
Nasopharyngitis	10 (5%)	11 (5%)	1 (1%)
Fatigue	12 (6%)	8 (4%)	3 (3%)
Anxiety	8 (4%)	10 (5%)	5 (5%)
Drug withdrawal syndrome	7 (3%)	9 (4%)	6 (6%)
Blood creatine phosphokinase increase	5 (2%)	11 (5%)	1 (1%)
Diarrhoea	5 (2%)	5 (2%)	5 (5%)

*Reported in at least 5% of participants in any treatment group during the double-blind phase.

Table 4: Treatment-emergent adverse events (safety analysis set)

Haight, et al. Lancet 2019

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Study Conclusions

- XR buprenorphine showed improved retention and abstinence rates vs placebo
- No difference in retention or abstinence between treatment groups (300mg vs 100mg step-down)
- Similar SEs to SL bup (with the addition of injection site reactions (pruritis/pain)
- NB: This study was heavily influenced by Indivior.
- The comparison is PLACEBO!

Haight, et al. Lancet 2019

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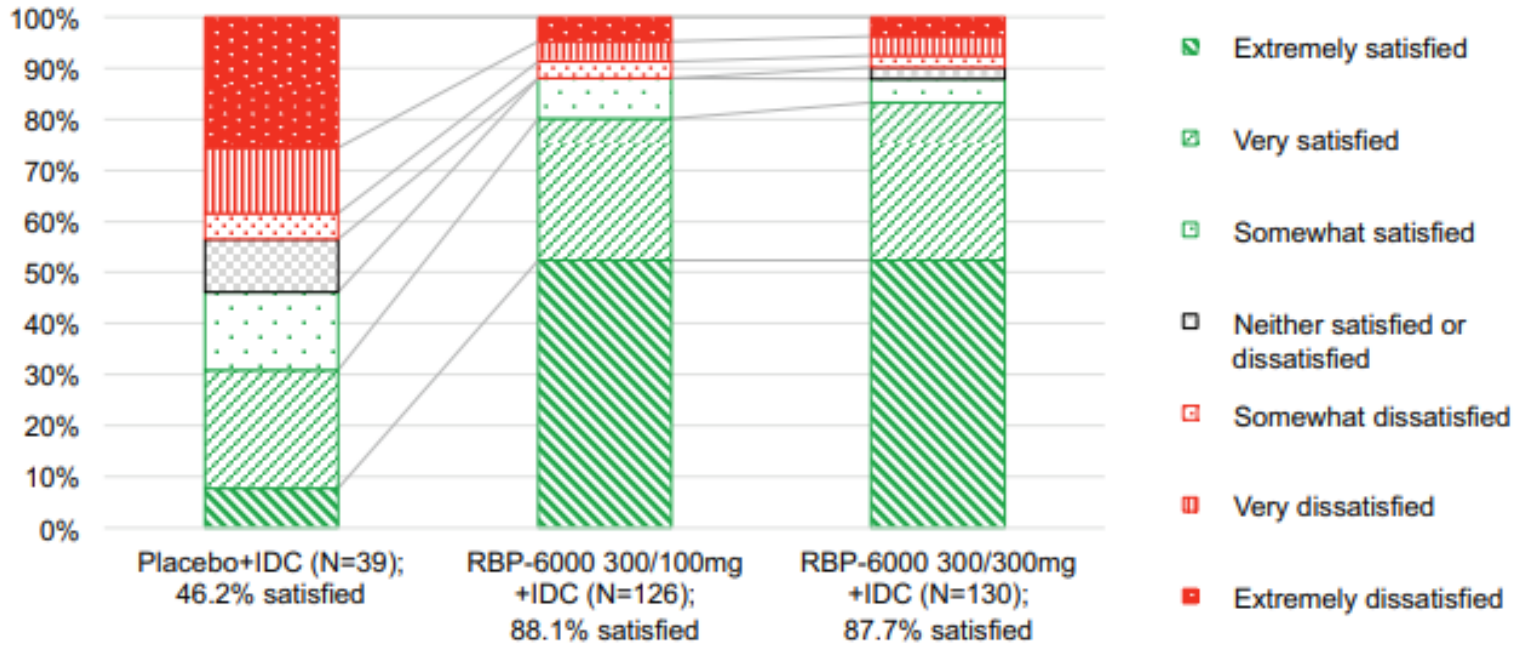
Tertiary, patient-centered outcomes were collected during the trial.

Patient satisfaction at week 25:



Ling et al. J Addict Med, 2019

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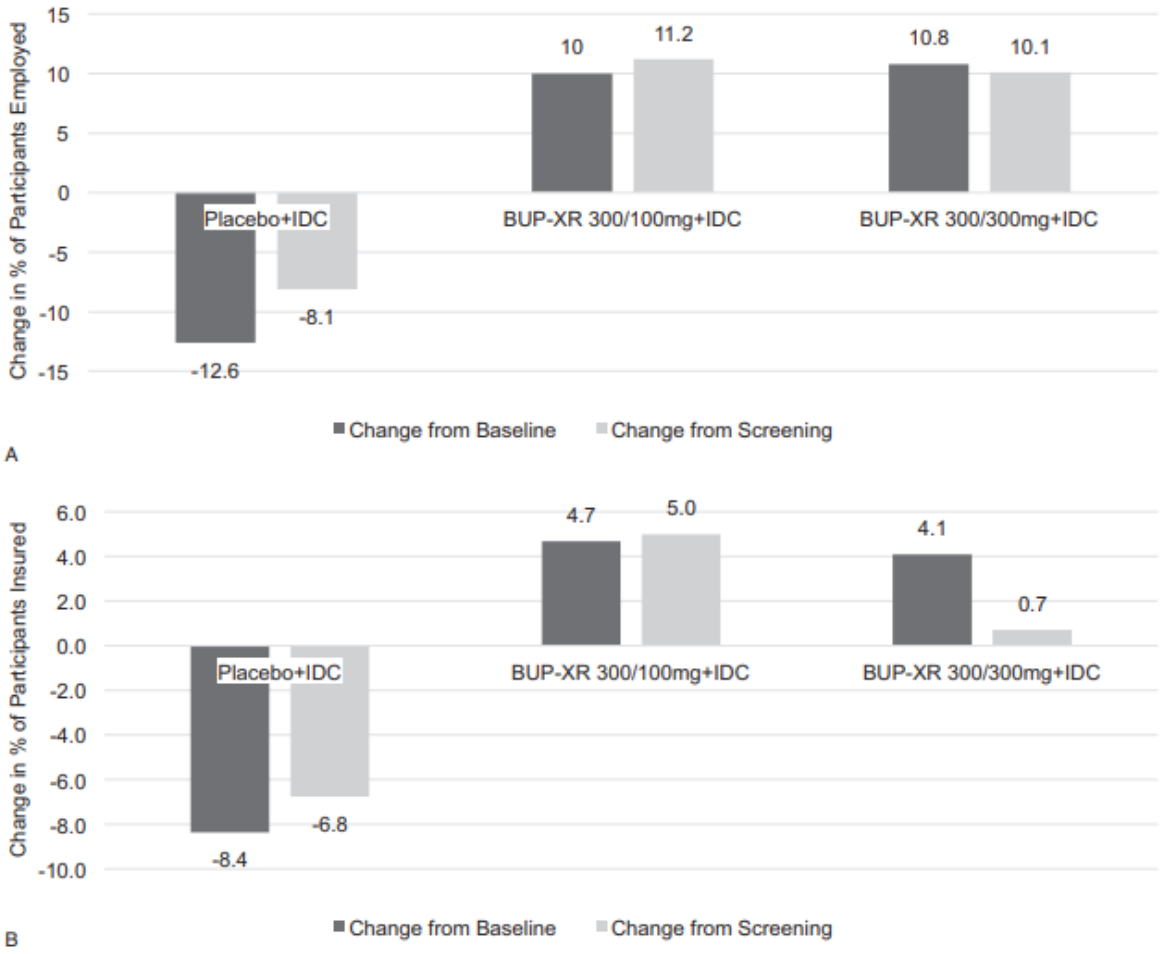

Ling et al, J Addict Med, 2019

- No direct comparison of Sublocade to SL buprenorphine. However, in an RCT of 428 participants, Brixadi (CAM 2038) XR SQ buprenorphine (not yet available in US) was non-inferior to SL buprenorphine for retention and reduction in extra-medical opioid use.
- In another randomized study examining patient-centered outcomes, XR bup (Brixadi) recipients had greater treatment satisfaction vs SL buprenorphine.

Lofwall, et al, JAMA Intern Med. 2018; Lintzeris et al, JAMA Netw Open. 2021

Real World Study

- Retrospective case series of 40 patients.
- Recruited at MGH Bridge clinic.
- Patients were mostly male (67.5%), non-Hispanic white (97.5%), unstably housed (77.5%) and average age of 32.1.

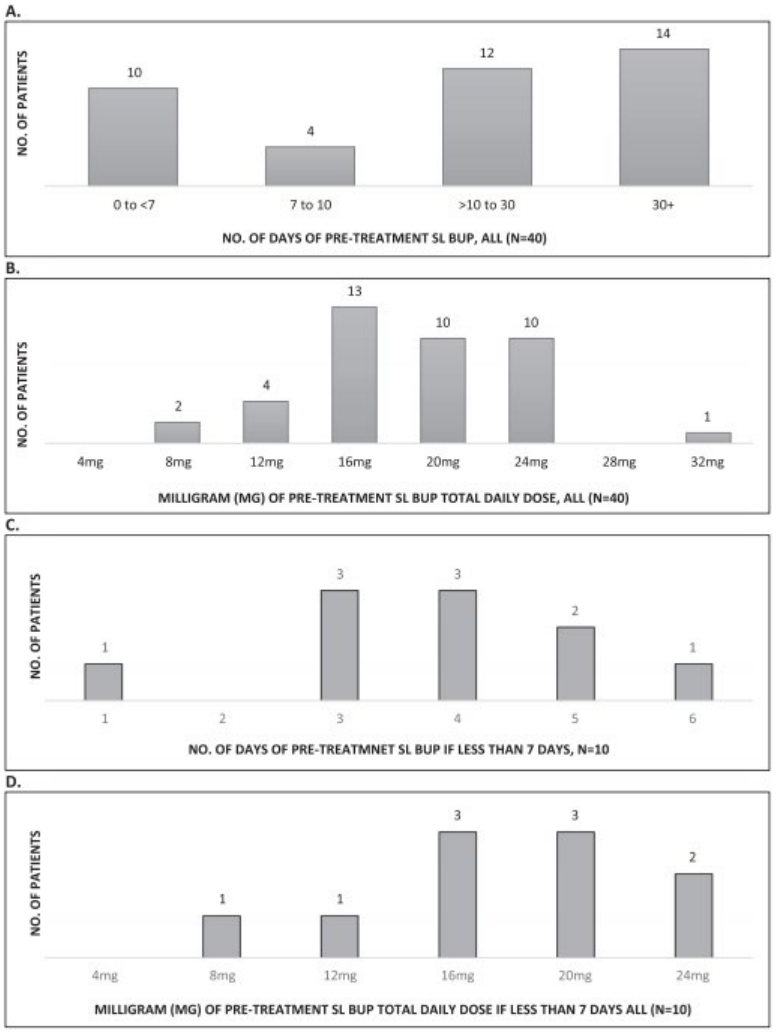

Fig. 1. Pre-treatment dosage and days of therapy with sublingual buprenorphine (SL BUP).

Peckham et al, Journal of Substance Abuse Treatment, 2021

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- 25% remained on high-dose XR-bup (300mg monthly)
- 55% required supplemental SL Bup (4-24mg) at some point
- Retention:
  - 67.5% remained on XR-bup
  - 30% discontinued (most cited reaason was preference for SL bup)
  - One was lost to follow up
- Illicit opioid negative UDS 65%
- No precipitated withdrawal. No overdoses.

Peckham et al, Journal of Substance Abuse Treatment, 2021

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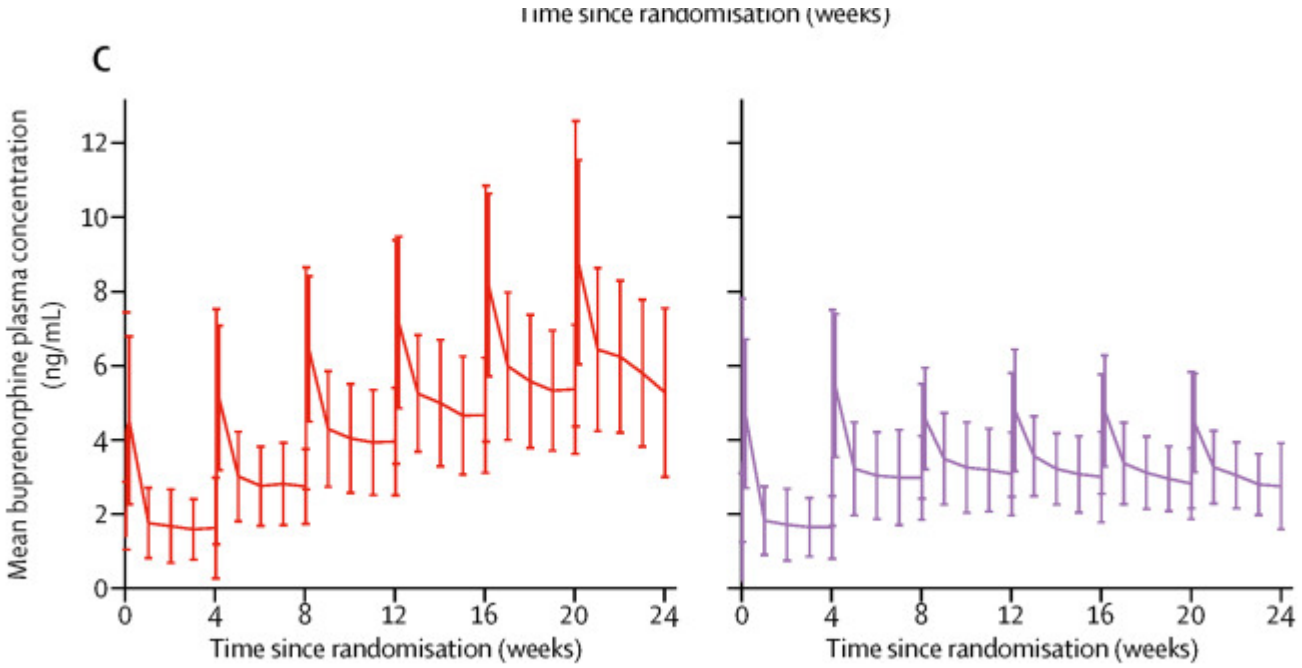
Serum Levels and dosing

- Steady-state achieved in 6 months for the 300mg group
- Steady-state achieved in 2 months for the 100mg group



Haight, et al. Lancet 2019

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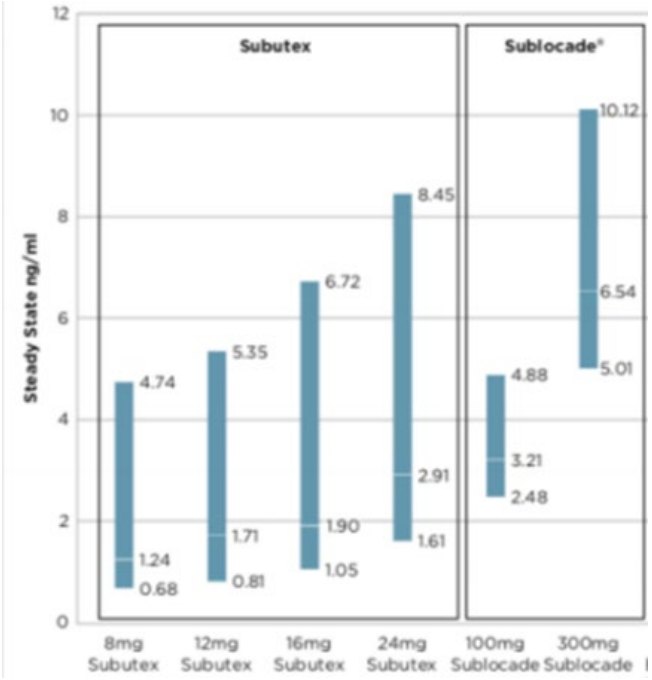
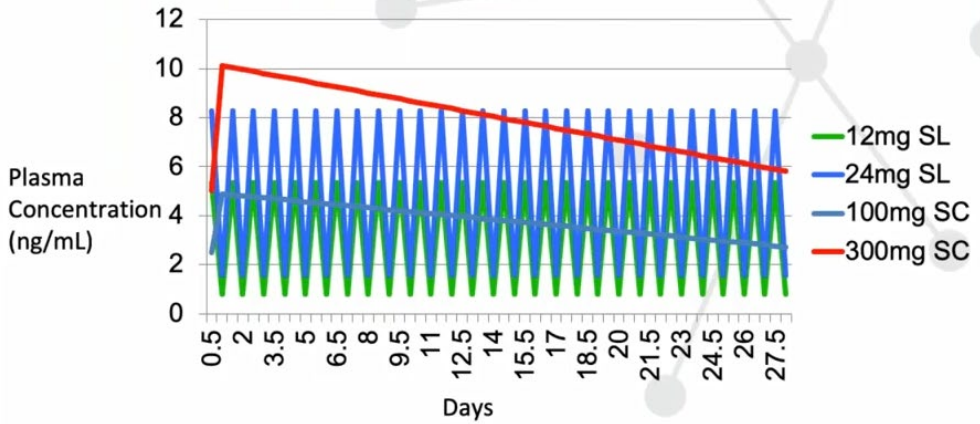


Serum Concentrations of Different Formulations



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Dosing considerations

For folks who continue to use extra-medical opioids or experience cravings after their second injection of 300mg, it is reasonable to consider staying at 300mg.

For folks who experience increased instability or craving after reduction to 100mg, it is reasonable to consider increasing back to 300mg

Supplemental SL dosing may be necessary for some patients who continue to experience craving or withdrawal after their first few injections.

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Troubleshooting

- In general, if a patient is late for an injection appointment, they can be administered the dose within 2 weeks without compromising treatment or risking precipitated withdrawal.
- Patients may test positive for buprenorphine months after last injection.

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Take Home Points

- Injectable XR buprenorphine may be a good option for patients where there are concerns around diversion, regular adherence, regular attendance for monitoring.
- Favorable safety profile with adverse events similar to SL, plus some general mild injection site reactions
- No direct comparisons to SL buprenorphine for the available formulation.
- Some patients may need supplemental SL “top-off” dosing. Some may need to remain at 300mg instead of stepping down.

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Panel Discussion

What has been the experience for patients undergoing “microdosing” inductions in the hospital?

What do you see as the benefits and drawbacks of injectable XR buprenorphine in your practice and which population of patients may be most appropriate?

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