Research Meets Practice
Treatment of Opioid Dependence in a Private Office

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Background

- Methadone has been the only approved treatment for over 30 years
- Must be distributed only in special clinics
- Associated with stigma
- In early 1900's doctors maintained opiate abusers with morphine in offices.
- Many incarcerated

Background

- Medical Maintenance methadone model
- Buprenorphine/naloxone Study 1995-98
- Safety and efficacy established
- 1998 NIDA Medications Development proposed a “ best practices study” with the Veterans Administration to evaluate use of the medication in non-traditional settings

NIDA/VA Study 1018

Robert Walsh, Frank Vocci, Walter Ling, Paul Fudala

- Research conducted in non-methadone settings
- Required following protocol, completion of case report forms, submission, review
- The national study involved 38 investigators with 583 patients (New York, California, Washington State, Texas, Florida, Illinois) in a variety of treatment settings

Purpose of the Study

- Evaluate safety in a non-research setting
- Offer clinicians experience in use of the medication in non-traditional settings.
- Assess physician prescribing practices.
- Assess clinician and patient satisfaction.
- Allow integration of practice and research

Procedures

- Open Label/No randomization-52 weeks
- Conducted in a solo psychiatry practice in a residential neighborhood New York City.
- On-site drug urine drug screening
- On-site or laboratory pregnancy testing
- Medication dispensed in local pharmacy

Bup/Nx Treatment of Opioid Dependence

Inclusion Criteria

- 15 years or older
- Seeking treatment
- DSM IV Criteria for opiate dependence
- Able to sign informed consent.
- Good physical/mental health

Exclusion Criteria

- Unstable medical or psychiatric condition
- Dependent on alcohol, benzodiazepines or other drugs of abuse
- Methadone/LAAM use in prior 30 days.
- Current participation in a research study
- Pregnant/lactating female

Treatment Schedule

- Week 1 — 2 visits
- Weeks 2-12 — Weekly visits
- Weeks 13-26 — Bi-weekly visits
- Weeks 27-52 — Monthly visits

Visit schedule based on patient response, functioning

Drug screens weekly(1-9) and random 10-52

Treatment Phases

- ***Induction:*** Daily contact required
- ***Stabilization:*** Comfort and function attained
- ***Maintenance:*** Goal is discontinued use Relapse prevention strategies integrated.
- ***Taper***: Based on individualized plan, ancillary medications for last weeks.

Results (40)

Median Age	35
Age Range	21-49
Sex	25 Male 15 Female
Race	38 White 02 AA
HIV +	03
Median maintenance dose	12 mg

Drug Use at Screening

IV Heroin	16	40%
Smoke/snort	18	45%
Pain medications	04	10%
Smoked opium	02	05%
Cocaine Use	23	57%
Benzodiazepines	10	25%

Employment

- Employed/Self Employed 78%
- Students 12%
- Psychiatric Disability 10%

Occupations

- Psychologist
- Architects (2)
- Attorney
- Journalist
- Hair Stylists(2)
- Plumber
- Construction Worker
- Disco Manager
- Salesman
- Students (5)
- Stone Mason
- Exterminator
- Business exec
- Housewife

Treatment response

- Of the 34 patients who remained in treatment longer than 2 months all were generally compliant
- 15/34 discontinued opiate use within 4 weeks
- 10 continued reduced use over a 3-6 month period, primarily in social situations, then stopped.
- 9/34 used sporadically past 6 months, continued in treatment and were productive citizens.

Previous Treatment

Buprenorphine Detoxification	8	(20%)
Methadone Maintenance	12	(30%)
LAAM Maintenance	4	(10%)
Therapeutic Community	2	(05%)
Outpatient Detoxification	16	(40%)
Inpatient Detoxification	5	(13%)
UROD	1	(02%)
No Previous Treatment	7	(18%)

Adverse Effects

- Buprenorphine/naloxone has been demonstrated to be safe and effective. In this group there were no serious adverse events related to medication.
- The most frequent reported side effects occurred primarily during the stabilization period and included fatigue, headache, impotence, sleep disorder, constipation and sweating.
- During stabilization, dysphoria was frequently reported and improved with SSRI treatment.

Patient Education Issues

- All were warned to closely guard the medicine, there would be no replacements
- All were advised not to adjust doses without a call, but in fact several who wanted to use opiates learned how to stop and start the medication. The safety of the medication allowed provider comfort.

Bi-weekly or Monthly Visits

- During the first weeks of the study, patients were compliant with appointments.
- Over time, appointments were not rigorously kept.
- Frequent appointment changes also were an alert that medication was not taken as prescribed.

Office Management

- Carefully screen prior to consultation
- Outline expectations
- Define unacceptable behaviors
- Agree on treatment goals
- On-site drug testing assists treatment
- Random pill counts helps limit diversion
- Appointment compliance promotes responsibility
- Patients may see the MD as the new dealer- manifested by coming only for medication.

Who Does Well?

- The majority of patients in this sample were employed, goal directed, secret users, and primarily used opiates. Many had previous treatment and were ready to change. These needed little in the way of social services or counseling. Medication alone returned them to functioning.
- Four were on psychiatric disability, enrolled in intensive outpatient programs and also did well.

Who has more difficulty?

- The Ambivalent patient
- The user who wants to “feel” a medication
- Patients unwilling to take personal responsibility
- Those unable to tolerate minimal structure

End of Study

- Taper schedules were individualized.
- Relapse concerns, anger at not being able to continue and anxiety were common.
- Four have traveled to France to obtain drug
- Six month follow-up

Relapsed, returned to treatment

Drug-free

Six months later

Telephone contact, self-report

Remain drug-free	*11*	*28%*
Obtained buprenophine	*04*	*10%*
Sporadic use	*11*	*28%*
Relapsed, returned to treatment	*09*	*22%*
Relapsed, no treatment	*04*	*10%*
Lost to follow-up	*01*	*02%*

Patient Satisfaction

- All expressed satisfaction with the office model, liked the privacy and flexibility of scheduling around their professional needs.
- The medication was preferred over methadone or LAAM, had few side effects, no sedative effect. None reported euphoria, but did state they felt content. All remaining a year wanted to continue.

Discussion

- Office treatment requires procedural adjustments.
- Set limits, require treatment compliance.
- You will need a flexible approach.
- Integrate psychological and behavioral treatment with medication to avoid being seen as a new drug supplier.

Conclusions

- Office based model is feasible and desirable
- Medication with counseling is sufficient for higher functioning individuals
- Diversion will occur.
- Non-compliance should be addressed in treatment.
- A non-punitive approach works well