High dose buprenorphine may be an effective interim treatment for long term heroin users waiting for drug-assisted rehabilitation


QUESTION: Can buprenorphine, without psychosocial treatment, help people waiting for drug-assisted rehabilitation from opiate dependency?

Design
Randomised controlled trial. Participants and staff were blind to treatment allocation, although they could guess allocation based on treatment effects.

Setting
Oslo, Norway.

Participants
106 people dependent on opioids (DSM-IV criteria) who had attempted traditional drug-free treatment in the past; 66% men; mean age 38 years; mean history of injecting heroin 20 years. All had polysubstance dependence, most commonly with cannabis or benzodiazepines. Exclusion criteria were age under 25 years; less than 10 years opiate dependence; pregnancy or serious illness.

Intervention
12 weeks of buprenorphine or placebo as interim treatment while participants awaited drug-assisted rehabilitation. Sublingual tablets were given under supervision each weekday, with a double dose on Saturdays and no dose on Sundays. Take-home doses were prohibited. On day 1, both groups received 4mg buprenorphine. Over approximately the next week, the intervention group’s dose increased to 16mg per day and the placebo dose reduced to 0mg. There was no additional psychosocial support or counselling.

Main outcome measures
Retention; compliance (percent of doses taken per day of participation); well-being; mental health; self-reported drug use.

Main results
Mean participation was 42 days for the buprenorphine group and 14 days for placebo (p <0.001). After 12 weeks, retention was 29% for the buprenorphine group and 2% for placebo. Compliance was equal between groups after controlling for participation (85% for placebo v 83% for buprenorphine). People receiving buprenorphine reported a greater reduction in the use of heroin, other drugs and alcohol. They also reported increased wellbeing and life satisfaction (all p <0.05).

There were no deaths or serious adverse effects.

Conclusions
People on waiting lists for heroin rehabilitation may benefit from buprenorphine in the interim. It was difficult for participants to remain in the programme without psychosocial support.

COMMENTARY
This useful study continues the tradition of combining limited opiate substitution with a placebo controlled trial of efficacy. Limiting access to opiate substitution treatment provides the only practical opportunity for trials since participants are generally not prepared to accept a ‘no medication’ option. In these situations, there may be some reluctance from the broader community to make opiate substitution widely available. Trials such as this have local political, as well as broader scientific, implications.

A number of similar studies have been conducted with methadone. All found that methadone substitution led to less heroin use than placebo, detoxification, no treatment or waitlist control. There have been two short term placebo controlled studies of buprenorphine. After 10 days of buprenorphine treatment (4–8mg v placebo), opiate dependent volunteers taking buprenorphine took money in preference for heroin while those taking placebo did not. A larger study also found reduced heroin use compared to placebo.

Krook’s study is not a ‘true’ placebo controlled trial because the blind was ineffective and the placebo group received 10 days of reducing buprenorphine which many participants reported as the best detox they had ever done. In effect it is a comparison of detoxification (placebo) without counselling versus low dose maintenance without counselling. Less heroin use in the low dose maintenance group is consistent with previous research and adds to evidence supporting opiate substitution treatment.

The heroin use outcome measures are the main methodological problem. There was no objective measure of heroin use and visual analogue scales were used for self report data. The strict rules for study participants (attendance at the appointed time and exclusion of those who missed 4 or more days) may lead to a higher drop out rate than would be expected in a more flexible programme. Likewise, many from the detoxification (placebo) group could be expected to seek repeat treatment if available.

Despite these limits, the study suggests that opiate substitution, even without counselling, is beneficial in the short term. Low dose buprenorphine is particularly suitable for low threshold substitution treatment since effective doses are probably safer in overdose than methadone. While low threshold programmes can provide a low cost alternative to more comprehensive programmes and may even be preferred by some heroin users, care must be taken to ensure that they do not replace individually tailored opiate substitution, which has been found to be safe and highly cost effective.

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