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▶ Is heroin-assisted treatment effective for patients with no previous maintenance treatment? Results from a German randomised controlled trial.

Haasen C., Verthein U., Eiroa-Orosa F.J. et al.
European Addiction Research: 2010, 16, p. 124–130.
Request reprint using your default e-mail program or write to Dr Haasen at haasen@uke.uni-hamburg.de

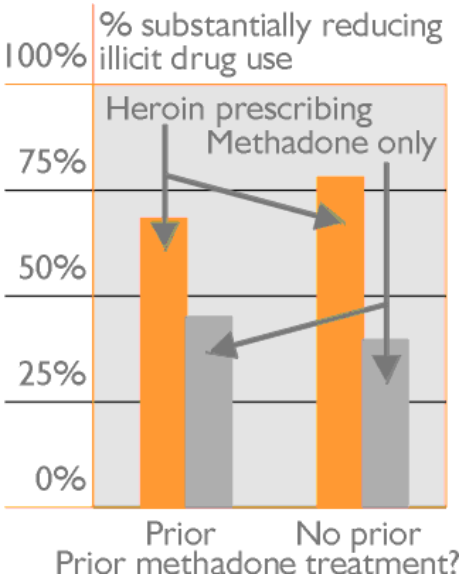
Uniquely among modern heroin prescribing trials, the trial in Germany was not confined to heroin-addicted patients who had done poorly on methadone, offering the opportunity to assess whether heroin should be reserved for these patients. The conclusion was that other patients too benefit more from injectable heroin than oral methadone.

Summary This account also draws on the main report from the trial of which the featured report was a sub-study. The study trialled the prescribing of heroin for the treatment of heroin addiction at seven German clinics. Over the years 2002 and 2003 it successfully recruited 1015 patients who were continuing to regularly inject heroin and were in poor physical or mental health despite currently being in methadone maintenance treatment, or having been treated for their addiction in the past but not in the last six months. Uniquely among modern trials, because the past treatment need not have been opiate substitute prescribing, the trial was not confined to patients who had previously done poorly on methadone, offering the opportunity taken by the featured report to assess whether heroin prescribing should be reserved to these patients.

Patients were randomly allocated to either be prescribed heroin to be taken under supervision at the clinics plus oral methadone, or only oral methadone. Cutting across this allocation, they were also randomly allocated to two forms of psychosocial support: case management conducted along motivational interviewing lines and intended to flexibly coordinate an individualised care package from various services; or a more standard and directly delivered series of individual counselling and group therapy sessions. Which of these support programmes a patient was allocated to made no difference to the main outcomes, so reports have focused on the pharmacotherapy options.

Main findings

Over the next year 67% of the heroin patients remained in treatment but just 40% offered only methadone, a difference largely due to the 29% offered methadone who did not even start the treatment. Heroin enabled more patients than methadone (69% v. 55%) to substantially curb illicit heroin use without countervailing increases in cocaine use, and more heroin patients experienced improved health. If both together were considered the criterion for success, this was achieved by 57% on heroin but only 45% on methadone. However, many methadone patients also substantially cut their heroin use and experienced improved health despite previous treatment having left them still dependent on heroin.



The main report on the trial records that the heroin option was not significantly more or less advantageous for patients recruited from methadone programmes versus those not in treatment at all for at least the past six months. The featured report took this analysis a step further by identifying who among the 'not in treatment patients' patients had never been in methadone maintenance treatment. How they responded to the offer of heroin could then be compared against the rest of the sample who had previously experienced methadone.

Around half the no-prior methadone patients stayed in treatment for the full 12 months of the follow-up regardless of whether they had been allocated to heroin or methadone. In terms of substantially curbing their heroin use without countervailing increases in cocaine use (▸ *chart*), patients with no previous experience of methadone maintenance were slightly more likely to do better if offered heroin as those previously on methadone, and on heroin they also committed crimes less frequently. Towards the end of the one-year follow-up, they also experienced non-significantly better health if prescribed heroin, and used cocaine less frequently. But it was also the case that – for the first time – trying methadone in the context of the trial also had a substantial if lesser impact on all these outcomes.

The authors' conclusions

The featured study was the first to analyse the effects of heroin prescribing treatment in patients with no previous experience of opiate substitute prescribing programmes. Its findings show that such patients benefit from both heroin prescribing and methadone

maintenance to almost the same degree as patients previously in methadone maintenance treatment. Despite having no personal negative experiences with methadone, these patients also respond better to heroin prescribing than to methadone in terms of reduced illicit drug use and illegal activity, generally considered the two main goals of maintenance treatment. These differences could not be explained by greater retention on heroin, since retention was roughly the same on methadone. Possibly the prospect of either being allocated to heroin or, if not, switching to this option after a year, attracted patients in to maintenance therapy which they had previously avoided, and helped retain them even when they had been allocated to methadone. If this was the case, the possibility of heroin prescribing played a valuable role in encouraging treatment entry, and actually being prescribed heroin benefited more patients than oral methadone only.

These results call in to question whether heroin prescribing should only be implemented only as a second line treatment following the failure of methadone programmes, or whether it should be made available to all chronic, severely opioid-dependent patients, regardless of their previous experience with methadone treatment.

FINDINGS No studies have directly assessed how wide is the caseload who could benefit from heroin substantially more than from the best feasible oral methadone regimen. Only Britain in the 60s and 70s has experience of heroin prescribing as a truly front line specialist treatment for heroin addiction, deployed to attract addicts in to the newly established drug dependence clinics. In these special circumstances it fulfilled that role, but doctors rapidly moved patients on to the new oral methadone option pioneered in the USA, an attempt to engineer a more therapeutic and normalising regimen which made drug use, the effects of drugs, and particularly injecting, less central to patients' lives.

In those days supervised consumption was a rarity. Today with national authorities insisting on or encouraging supervision, heroin prescribing is less of an incentive to enter treatment because it entails twice-daily clinic attendance – a substantial disincentive, and one reason why trials have found it very difficult to recruit patients. On the other hand, one of the main reasons for insisting on supervised consumption – to avoid heroin being diverted on to the illicit market – is less salient because illicit heroin is so widely available that a little spillage from clinics could make little difference to the size of the addiction problem. Nevertheless, other reasons for supervising consumption and the need for clinics to sustain public and political support seem likely to continue to mandate supervision, at least initially.

A key question about heroin prescribing – whether it should be reserved to patients who have repeatedly done poorly on methadone, or used to attract patients suffering badly from their addiction but who will not engage with methadone – cannot be decided on the basis of the available research in to its effectiveness, partly because this aspect has not been adequately researched, and partly because many other important considerations influence that decision. Some of the issues are explored further below; in the current climate, the decisive factor seems likely to be cost rather than cost-effectiveness.

Only for methadone's failures?

Across all studies to date, a synthesis of findings published in 2010 found that prescribing heroin as opposed to

oral methadone to patients who have generally not done well in methadone programmes promotes retention, reduces the risk of relapse to illicit heroin use, and reduces crime – consequences (which also extend to improved health and social situations) partly due to longer retention, and partly to the greater impact of heroin prescribing even among patients still in treatment. The analysts' conclusion was that heroin prescription should remain a treatment of last resort for people failed by conventional maintenance treatment. Similar conclusions are found in UK national clinical guidelines and in guidance issued by England's National Treatment Agency for Substance Misuse. In particular, the latter is clear that injectable prescribing should be considered only for the minority of patients with persistently poor outcomes despite optimised oral programmes, and that the priority should be improving the effectiveness of oral maintenance treatment for the majority.

Relatively high cost, the risk of perpetuating injecting, the heavy responsibility placed on staff to safeguard lives during the injections they supervise, and the burden on patients required to attend the clinic to take their heroin, are among the reasons why heroin prescribing is seen as a niche last resort for methadone's failures. But this also means patients are forced to suffer life-threatening failures in methadone programmes before being offered heroin, and that others who could have benefited from heroin will not be offered it because they are so averse to methadone that they have never engaged with that treatment. It is this dilemma which the featured study addresses, finding evidence which calls in to question the need to insist on prior failed methadone tretments.

However, even in this study heroin prescribing was very far from a front line treatment. It was implemented only after prior treatments had failed to create or sustain recovery from heroin addiction, for patients who injected their drugs, had been dependent on opiate-type drugs for at least five years and regularly using heroin for on average over ten, and who generally also used other drugs, including cocaine and benzodiazepines. This background had left them all with poor mental and/or physical health (a requirement for joining the study) and generally they were in a very poor state on both fronts, including eight in 10 infected with hepatitis C. In other words, even in this study heroin prescribing was a second line treatment implemented well in to the addiction careers of patients who had shown themselves willing to continue to inject heroin nearly every day despite very serious ill health and prior attempts to stop.

Though the study was not set up to test the impact of prior failed methadone treatment, random allocation should have meant that differences between patients could not account for any extra benefit of prescribing heroin compared to methadone. Confirming this expectation, on all but one of 22 variables assessed by the study, the no-prior methadone patients allocated to heroin did not significantly differ from those offered only methadone.

The most recent British trial was confined to people continuing to inject illicit heroin despite being in methadone treatment, but it too offered some evidence that heroin can attract and retain patients who would not engage with oral methadone. The questions posed by the study were whether patients who remained wedded to illegal heroin despite extensive treatment were simply beyond available treatments, whether they needed injectable medications, or whether it was just that their current oral treatments were sub-optimal. For some, each of these three propositions was true. A third did seem beyond current treatments even as extended and optimised by the study. For a fifth, 'all' it took was to individualise and optimise dosing, psychosocial support and treatment planning in a continuing oral methadone programme. But despite these attempts to make the most of oral methadone, nearly half the patients only did well if prescribed injectable medications. A subsidiary finding was the unacceptability of oral methadone to many patients who did not start the treatment or who did but attended poorly, a sign perhaps that addicts who reject methadone maintenance, as well as those who try it but do not do well, may benefit from being prescribed heroin. Since missed urine tests were counted as positive, the unacceptability of methadone may have accounted for much of the greater reduction in illicit heroin use when the drug was legally prescribed.

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