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▶ The Andalusian trial on heroin-assisted treatment: a 2 year follow-up.

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Oviedo-Joekes E., March J.C., Romero M. et al.
Drug and Alcohol Review: 2010, 29(1), p. 75–80.
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Heroin/cocaine addicts in Granada in Spain who were being prescribed heroin made greater sustained improvements in their illicit heroin use, crime and psychological health and showed signs of more social reintegration than patients who nearly three years before had been randomly allocated to methadone.

Summary Deriving from a study in Granada in Spain, the featured report is based on re-interviews with 54 of 62 patients addicted to heroin/cocaine, on average just over two years after the end of a nine-month period during which they had been randomly allocated to oral methadone maintenance, or this plus injectable heroin consumed under supervision at the clinic twice a day. To enter the trial patients had to be injecting opiates despite having been in methadone treatment at least twice in the past, and to be suffering from at least two of: injecting-related infectious disease; mental health problems; substantial social/family problems or criminal activity.

After the nine months during which they had been randomly allocated to heroin or methadone, patients still being prescribed heroin were allowed to continue, and those prescribed only methadone could be switched to heroin (13 of 31 were) if they wanted to and if they met legal criteria for this option as a 'compassionate treatment'. At the final follow-up this created three groups: patients currently being prescribed heroin after being randomly allocated to it or switched from methadone-only; patients prescribed heroin but who had discontinued this treatment; patients allocated to methadone-only and never subsequently prescribed heroin. The featured report compares long-term outcomes between these categories. An earlier paper also drawn on in this account reported on outcomes during the nine-month randomisation period.

Main findings: nine-month randomised trial

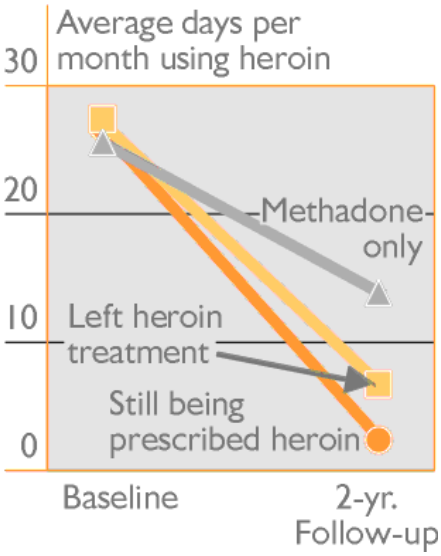
Just over 7 in 10 patients stayed in treatment for the first nine months of the trial, more or less regardless of whether they had been allocated to heroin or methadone only. However, by the end heroin patients had improved more in their experience of feeling unwell, in reducing their heroin use (down from 23–24 days to eight in the past month compared to 17 among patients prescribed only methadone), their risk of contracting infectious disease due to their drugtaking practices, and their criminal activity. The patients' assessments of their quality of life and family and social relationships were not significantly affected by the treatment to which they had been allocated.

Though heroin patients had in some respects improved more, both sets of patients had generally improved on a variety of fronts, a testament to the benefits of an optimised methadone regimen (adequate doses and psychosocial support) as well as the extra gains available by prescribing injectable heroin to patients for whom methadone had previously proved insufficient.

These findings and those in the featured report derived from a highly selected set of patients who met the study's criteria of substantial medical, psychological or social problems, yet seemed able and willing to comply with a treatment involving clinic attendance twice a day nearly every day.

Main findings: two-year follow-up

Two years after the end of the nine months of the randomised trial, two of the 54 patients who could be recontacted were out of treatment, three were in drug-free treatment, 24 were being prescribed heroin, and 25 were in methadone maintenance treatment. Seven were in prison.



Though no longer in their randomised sets, the three groups compared at the two-year follow-up did not differ on the characteristics assessed at the beginning of the study. At the two-year follow-up all three were on average using heroin on many fewer days a month, but the reduction had been significantly steeper (down to just over two days) among patients still being prescribed heroin than among those who had been in the past (down to nearly seven days) or those only prescribed methadone (nearly 13 days) ▶ *chart*. Associated at least partly with the degree to which injecting had been reduced, patients still being prescribed heroin had made the greatest reduction in their risk of contracting infectious disease, those offered only methadone the least. Other statistically significant differences were the greater improvements in psychological health recorded by

patients still prescribed heroin.

In an analysis confined to patients not in jail, those on heroin had also committed crimes on the fewest days in the past month (eight), but this was not significantly different from the reductions in crime recorded among patients at some time prescribed heroin (to 21 days) or those only prescribed methadone (to 10 days). Among other non-significant differences, a higher proportion of patients still being prescribed heroin had worked in the month before the two-year follow-up (54%), a lower proportion were on welfare benefits (42%), and their self-experienced health had improved more than among the other two groups. There was no evidence that patients still being prescribed heroin had on average increased their use of other drugs; binge drinking and use of cannabis or illicit benzodiazepines had all decreased. Apart from reduced heroin use, the general picture among patients prescribed only methadone was that little had improved in their lives or in their physical and mental welfare since the start of the study. Patients prescribed heroin in the past but no longer were generally intermediate, and those still being prescribed heroin had improved most.

The authors' conclusions

Two years after the completion of the randomised trial, all patients had reduced their criminality, illicit heroin use and HIV risk behaviours, but those still being prescribed heroin had made the greatest improvements and were the only patients to on average experience improvements in their health and related quality of life.

These finding and those from a German trial show that the marked improvement observed in the first months of heroin prescribing can be sustained long-term. It should however be remembered that these results were achieved with a highly selected set of patients who were offered not just heroin, but for nine months the enhanced psychosocial support also available to patients prescribed methadone.

This study proves that heroin prescribing has a role in the addiction treatment system for a small group of severely affected opioid-dependent individuals. It provides further evidence that more so than methadone, the treatment can stabilise and improve the physical and mental health of some long-term heroin users with severe co-morbidities and high mortality who would otherwise impose a substantial burden on the health care system.

FINDINGS Replacement after nine months of an allocation to comparison groups based entirely on randomisation, by one governed more by patient choice, life events and clinical judgement, means that the outcome differences documented in the featured report were no longer purely a function of the treatment options being compared. Despite their apparent similarities, patients who managed to stay in heroin treatment, those who qualified and chose (or not) to transfer from methadone, and those who chose or had to leave heroin treatment, may differ in their circumstances in ways which substantially affected the outcomes. Most importantly, the implication that staying in heroin treatment was the best option must be tempered by the possibility that patients who already had most going for them held on to their heroin prescription by complying with the onerous attendance requirements imposed throughout the follow-up period.

However, the authors cautioned against assuming that patients who dropped out of heroin treatment had not responded well to that option; in the first nine months of the

trial, treatment leavers were actually less problematic than treatment completers on the variables assessed by the study. This reinforces the conclusion that staying in treatment was an active ingredient in the success achieved by heroin patients, in line with other heroin prescribing studies (▶ below) and the literature on opiate substitute prescribing in general. Such treatments tend to work like an on-off switch; while patients are in treatment, most quickly improve and do relatively well, but rapid reversion to regular illicit heroin use with all its consequences is common if they drop out or are forced out of treatment.

Notably, not only did patients still in heroin treatment use illicit heroin less often, they were also more likely to be socially integrated in terms of working, not reliant on welfare benefits, and having non-drug using friends, confounding fears that prescribing heroin would simply sustain them in an unsatisfactory drug-focused lifestyle.

The key issue now is not whether some patients benefit in these and other ways from being prescribed heroin – it is clear that they do – but who benefits and to whom this option should be offered. Like nearly all other trials, the featured study reserved heroin for people who had repeatedly done poorly on oral methadone. British guidance too sees this as the treatment's role, but there are hints in the research that this may exclude patients who would do well on heroin but reject methadone; more ▶ below.

Guidance on heroin prescribing

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.

Only for methadone's failures?

High cost, the risk of perpetuating injecting and opiate use, the heavy responsibility placed on staff to safeguard lives during the injections they supervise, and the burden on patients required to attend clinics to take their heroin, are among the reasons why heroin prescribing is seen as a niche last resort for methadone's failures. On the other hand, this caution means patients are forced to suffer life-threatening relapses during or after methadone programmes before being offered heroin, and that others who could have benefited from heroin will not be offered it because they are so unattracted to methadone that they have never engaged with that treatment.

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, but a report from the German heroin prescribing trial has cast doubt on the rationale for insisting on prior methadone treatment. The study was confined to patients who despite previous treatment were still addicted to heroin, but uniquely among modern supervised consumption trials, the prior treatment need not have been opiate substitute prescribing. Like the featured study, patients had been randomly allocated to heroin plus methadone or methadone alone. In terms of substantially curbing their heroin use without countervailing increases in cocaine use, patients with no previous experience of

methadone maintenance were as or more likely to do better if offered heroin as those previously on methadone. Towards the end of the one-year follow-up they also experienced non-significantly better health if prescribed heroin.

The most recent British trial was confined to people continuing to inject illicit heroin despite being in methadone treatment. At random, they were allocated to continue on an improved oral methadone regimen or to be prescribed injectable heroin or methadone. The questions posed by the study were whether these 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. In turn this suggests that addicts who reject oral 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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