Opioid abuse: will tamper-proof oxycodone help?

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### Summary

A new 'abuse-deterrent' formulation of oxycodone hydrochloride modified-release tablets was released in April 2014, replacing the previous formulation that was easier for injecting drug users to abuse.

Evidence from the USA, where tamper-proof oxycodone was introduced in 2010, suggests that the deterrent is working.

However, some injecting drug users have found ways to use the new formulation and others appear to have switched to other prescription opioids.

What more can be done?

### Practice points

- Be alert for patients wanting to switch from the new oxycodone hydrochloride formulation, as it is possible they may be using it intranasally, intravenously or diverting it.\(^1\)\(^2\)
- Consider establishing patient identity and using the Prescription Shopping Information Service routinely for patients, especially when you are concerned about potential opioid misuse.\(^3\)\(^4\)
- Be aware that the new formulation of oxycodone is contraindicated in patients with mechanical bowel obstruction and use with caution in patients who have difficulty swallowing or are predisposed to intestinal obstruction.\(^5\)
- Instructions for taking the new formulation of oxycodone differ from those for the old formulation. Tablets must not be wet, licked or pre-soaked before taking, and each tablet must be separately swallowed with water.\(^6\)
- As for the old formulation, tablets are to be swallowed whole, not cut, broken, chewed, crushed or dissolved — this could lead to rapid release and absorption of a potentially fatal dose of oxycodone.\(^7\)

### Move to tamper-proof oxycodone

A new ‘tamper-proof’ formulation of oxycodone hydrochloride was released in Australia on 1 April this year, with the aim of reducing opioid abuse.\(^2\) At the same time the old non-tamper-proof formulation was withdrawn, and the lowest dose (5 mg) deleted from the PBS.\(^3\)
The new tablets are bulkier, designed to be difficult to crush, cut, break or chew and harder to dissolve, making them less amenable to injecting or snorting. Injecting is particularly difficult because the new formulation forms a viscous hydrogel on mixing with water, which will not easily pass through a needle.

However, it is still possible for the medicine to be misused by oral, intravenous and intranasal routes.

**Does tamper-proof oxycodone reduce abuse?**

Tamper-proof oxycodone was released in the USA in August 2010. Since then published studies and postmarketing surveillance have examined the effect of the reformulation on abuse of oxycodone itself and of prescription opioids generally.

There is good evidence that abusers do not find the new oxycodone formulation as easy to use as the old one. Oxycodone is now less favoured by abusers across all routes of administration and particularly for snorting and injecting.

For example, in an NEJM survey of more than 2500 patients with prescription opioid dependence, while 35.6% of respondents said oxycodone was their preferred ‘drug of abuse’ before the reformulation, 21 months after reformulation introduction the number reduced to 12.8%.

**Abusers may switch to another opioid**

However, as oxycodone fell out of favour with abusers, many turned to other prescription opioids. The NEJM study reported a significant rise in use of high-potency fentanyl and hydromorphone, as well as a doubling of heroin abuse.

This study concluded ‘there was no evidence that oxycodone abusers ceased their drug abuse as a result of the abuse-deterrent formulation … they simply shifted their drug of choice.’

Another study showed that abuse of buprenorphine and oxymorphone* among more than 230,000 substance abusers rose markedly when the oxycodone reformulation was released.

The rise in abuse of buprenorphine was strongest among injecting abusers, where the relative risk of use was nearly six times higher after the introduction of reformulated oxycodone. However, this study, reported in *Pain Medicine*, found no evidence of a rise in heroin use.

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* Oxymorphone is not available in Australia.

**No change in overall abuse**

Although opioid abusers clearly avoid the new formulation, evidence is lacking that it has led to an overall decrease in the prevalence of oxycodone abuse.

Reviewing postmarketing studies, the FDA concluded ‘the data do not yet demonstrate a reduction in Oxycontin abuse following the replacement of Oxycontin with reformulated Oxycontin in the marketplace’.

There is also no evidence that it has reduced prescription opioid abuse in total. In the *Pain Medicine* study there was a small increase in abuse prevalence for all prescription opioids as a class.
Is overprescribing contributing to abuse?

Although still at low prevalence, non-medical pharmaceutical opioid use in Australia doubled from 0.2% of the population to 0.4% between 2007 and 2010.¹

Australian opioid abusers are choosing to inject oxycodone more often. The same study reported an increase in oxycodone injecting from 17% of Australian 'illicit drug users' in 2005 to 31% in 2013.²

The case for abuse-deterrent formulations of prescription opioids is made stronger by the increasing availability of opioids as prescribing rises.

Evidence is weak for opioids in chronic non-cancer pain

In the past decade, scripts written for oxycodone by Australian GPs have increased fourfold.¹⁰

Much of this increase is thought to be due to prescribing for chronic non-cancer pain, a condition estimated to affect about 20% of the population¹¹,¹² and for which meta-analysis shows no clear evidence regarding effectiveness.¹³

A 2010 Cochrane review revealed the paucity of studies on the long-term effectiveness of opioids for this indication, concluding that the evidence for the effectiveness of long-term opioid use for chronic non-cancer pain was 'too sparse to draw firm conclusions'.¹³

Yet according to more than 400 NSW GPs surveyed in 2011, a typical GP prescribes opioids for chronic non-cancer pain to a median of four patients each fortnight.¹⁴

To further complicate matters, patients with chronic non-cancer pain are more likely to have comorbid conditions that place them at greater risk of problematic medicine use.¹⁵

What are current prescribing patterns?

In another study using 2010/11 data, about 44% of GPs’ opioid prescriptions were for chronic non-cancer conditions. Only 3.5% of opioids were prescribed for pain caused by cancer, and the remainder (more than half) were presumably for acute conditions.¹⁶

Most prescriptions (58.2%) were for musculoskeletal problems, with back problems accounting for 27%. Osteoarthritis accounted for 9.7% and generalised multi-site pain for 6.6%.¹⁷

Considered prescribing is key

Although reformulated oxycodone may push opioid abusers to look for alternatives, the evidence so far from the USA suggests it will not reduce opioid abuse in total.¹⁸

There is scope for better adherence to guidelines: a recent survey found none of the 404 NSW GPs responding was compliant with all the local health district guidelines, and fewer than one third 'usually employed' most guideline items.¹⁴

Concordance with guidelines was lowest for strategies designed to reduce abuse, such as the management of aberrant behaviours. Only 16% reported often contacting the prescription shopping information service in the last 2 years when concerned about aberrant opioid behaviors.¹⁴

While an abuse-deterrent oxycodone formulation is now available, GPs can reduce the potential for abuse even more by adhering to prescribing guidelines.

Links to guidelines and other information sources
Expert commentary

'Re-launching psychoactive substances as abuse-proof has long been a strategy to avoid tighter regulations. “Abuse” is something clinicians naturally wish to prevent but it is subjective, hard to define and has recently lost its diagnostic status under DSM-5.1

‘Liberal prescribing may well be to blame. A US administrative database study observed over half a million cases with a first episode of chronic non-cancer pain and with no previous substance use history, comparing the prescription or not of opioid analgesics.

‘In those on high-dose opioids, rates of opioid abuse or dependency tripled if prescribed less than 90 days, and increased 122-fold if prescribed over 90 days.2

‘The reintroduction of liberal opioid therapy over the last two decades has seen the prevalence of use rise to 11.8% among adult Americans in 2010.3 This is despite the existing evidence not supporting their long-term efficacy and safety in chronic non-cancer pain.4

‘The strongest predictor of opioid prescribing has been found to be lower levels of clinician concern as to their negative effects.5 Clinicians should not let their commitment to quality pain management be distracted by an over-reliance on opioids, even when they are marketed as tamper-resistant.’

References


References
