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Pregabalin: the case for dialling back on a mediocre analgesic

Use should be more selective and driven by meaningful patient benefit

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Since its commercial launch in 2005, pregabalin has generated more than $50bn (£37bn; €44bn) in global revenue. Originally developed as an anticonvulsant, it became a "blockbuster" largely through its use for pain, including diabetic neuropathy, postherpetic neuralgia, fibromyalgia, and low back pain. Yet behind its commercial success lies a less flattering story: mounting evidence of harms ranging from oedema and weight gain to withdrawal, misuse, and death.

In a linked study, Cairns and colleagues (10.1136/bmj-2026-101021) examine prescribing patterns and overdose trends involving pregabalin in Australia.[1] Drawing on nine years of dispensing claims and poison centre data, they assessed changes following regulatory interventions (including tighter prescribing restrictions, strengthened safety warnings, and prescription monitoring) and media reports highlighting pregabalin's harms. Compared with projections based on earlier trends, prescriptions were 25% lower and intentional poisoning calls 47% lower than expected. The study is timely and rigorous, but these figures warrant caution. The ecological design cannot establish causation, and poison centre calls are an imperfect measure of poisoning incidence, influenced by reporting practices and patterns of healthcare use. Moreover, a separate analysis found no clear shift in poisoning call trends around the time of these measures. The departures from expected trends are striking; whether the interventions deserve the credit is another matter.

For all its popularity, pregabalin is a surprisingly middling analgesic. Although it can provide meaningful relief in some patients with neuropathic pain or fibromyalgia, most do not achieve substantial pain relief.[2 3] Even at higher doses, only a minority experience substantial additional benefit over placebo, while adverse effects become increasingly common. For other painful conditions, the evidence is even less encouraging. Randomised trials and meta-analyses have found no convincing evidence of benefit for low back pain or sciatica,[4] conditions for which the drug is nevertheless frequently prescribed. Pregabalin's commercial success, in other words, has far outstripped its demonstrated clinical utility.

Why, then, do we prescribe pregabalin so liberally? The answer is hardly a mystery. Pain is common, our patients want relief, and as clinicians, we are motivated to do something in the face of suffering. Prescribing a drug is immediate and tangible; evidence based non-pharmacological therapies such as exercise, physiotherapy, and cognitive-behavioural therapy[5] require time, effort, and resources that may not be readily available or covered by insurance. Moreover, pregabalin is widely perceived as safer than non-steroidal anti-inflammatory drugs and opioids, particularly for chronic use. With an already limited analgesic toolkit, it is little wonder that pregabalin has become an appealing choice, alone or in combination with other agents, even when the prospect of meaningful relief is remote.

Yet pregabalin's reputation for safety is not entirely deserved. Peripheral oedema and weight gain are common, dose related, and can easily escape recognition as adverse effects.[6] When co-prescribed with opioids, pregabalin is associated with an increased risk of opioid related death.[7] Physical dependence can develop even at therapeutic doses, sometimes after only weeks of treatment.[8] Abrupt dose reductions or discontinuation can precipitate a withdrawal syndrome characterised by anxiety, insomnia, agitation, and autonomic symptoms; seizures, hallucinations, and suicidal ideation have also been reported.[8 9] Nor are its hazards confined to patients taking it as prescribed. The drug is misused for its euphoric, sedating, and dissociative effects. Misuse is especially prevalent among people with substance use disorders, particularly people who use opioids, some of whom take pregabalin to intensify the effects of opioids.[10 11]

If the clinical picture is complicated, the regulatory one is hardly simpler. In France, tighter restrictions on pregabalin were followed by substantial declines in dispensing and co-prescribing with opioids and benzodiazepines.[12] In Egypt, reclassification was followed by a dramatic fall in sales but increased use of gabapentin and opioids.[13] By contrast, similar restrictions in England had little effect on prescribing, while deaths involving pregabalin continued to rise in England and Wales.[14 15] It is a familiar story in drug regulation: restricting access is easy enough; showing that patients are better off is harder to prove.

In short, we have come to regard pregabalin as an everyday analgesic that is safer and more effective than the evidence suggests. We should reserve it for conditions with established efficacy, such as diabetic neuropathy, postherpetic neuralgia and fibromyalgia, and avoid it for low back pain and sciatica where trials have found no convincing analgesic effect. Even for appropriate indications, treatment should continue only when patients experience meaningful improvement. The desire to relieve suffering is admirable and therapeutic optimism understandable. But persisting with ineffective treatment or relentlessly escalating the dose in pursuit of relief that has yet to materialise is no longer optimism. It is an invitation to harm.

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