



Proton pump inhibitors (PPIs)—too much of a good thing?

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KEY POINTS

- Gastrointestinal upset is a relatively common adverse effect of PPIs (greater than 1% of people)
- Other serious adverse effects include hyponatraemia, interstitial nephritis, *Clostridium difficile* and increased risk of pneumonia
- Two case-controlled studies^{1,2} have indicated that PPIs are associated with an increased risk of osteoporotic fracture, particularly hip fracture
- **Rebound and hypersecretion** can occur when proton pump inhibitors are discontinued leading to difficulty withdrawing—**down titrate slowly** over one to three months
- Use and dosage of proton pump inhibitors should be reviewed constantly (consider an H₂ antagonist)

Proton pump inhibitors (PPIs) such as omeprazole, pantoprazole and lansoprazole are one of the most commonly prescribed classes of medicines; one that some would consider to be overused. They are not a panacea for any gastrointestinal upset. Their indication is for GORD and peptic ulcer disease, and therapy is not necessarily lifelong.

While PPIs seem relatively innocuous, it is worth remembering that some of their frequent adverse effects involve the gastrointestinal system. This is an age-response relationship.³

Common (>1%) adverse effects include:

- constipation
- nausea/GI upset
- headache.

Less common/rare but serious adverse effects include:

- hyponatraemia and hypomagnesaemia, especially in the elderly
- interstitial nephritis
- insomnia, somnolence
- CNS effects
- arthralgia, myalgia, myopathy.

More recently there has been an association with:

- vitamin B12 deficiency
- *Clostridium difficile* infection
- community-acquired pneumonia.

Rebound and hypersecretion after proton pump inhibitors treatment

There is evidence of rebound hypersecretion after PPI therapy, particularly longer term therapy.³⁻¹⁰

There is no evidence of rebound hypersecretion after one week of PPI treatment^{11,12} but it has been demonstrated after eight weeks⁸ and can last more than eight weeks, but less than six months after long-term proton pump inhibition.⁴

The practical implication is that down titration of proton pump inhibitors needs to be slow, e.g. halve dose every one to three months if treatment has been long term, or the rebound symptoms will suggest that the original GORD symptoms have recurred. Persistence on the part of the patient is required if drug use is to be decreased.

Need for therapy? Bloating, nausea and reflux may be due to reduced gastric emptying (e.g. in the elderly). These symptoms may respond better to a prokinetic medicine such as domperidone.

Before starting a proton pump inhibitor:

Check if there is a clear indication that this is a condition in which lowering gastric acidity further will be of benefit—or is the symptom independent of acidity?

If the proton pump inhibitor doesn't 'work'

Check that the gastric symptom has not changed and whether the person is now experiencing a PPI adverse gastrointestinal effect.

Review three monthly—and try slow dose down titration.

If a PPI is prescribed on hospital discharge:

Check that this was not for 'prophylaxis' and stop if there is no clear indication for continued therapy.

NUGGETS of KNOWLEDGE provides succinct summaries of pharmaceutical evidence about treatment of common conditions presenting in primary care and possible adverse drug reactions.

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'Woe is me!': New Zealand's non-punitive regulatory environment

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"Given the absence of malpractice litigation in New Zealand, there is something rather self-indulgent in the response of the small minority of doctors who cry 'Woe is me!'"¹

This statement, written in 2006 by the then Health and Disability Commissioner, implies that doctors are not justified in crying 'woe in me' in response to New Zealand's regulatory system because it is somehow less woe-inducing, or less punishing, than malpractice litigation.

The New Zealand Medical Association has expressed a contrasting view:

"The New Zealand Medical Association is of the view that the medico-legal environment in New Zealand is a hostile one and constitutes a deterrent to good medical practice."²

This policy statement was written in 2002 and the Association may since have changed its view because subsequent legislative reforms in the mid-2000s streamlined New Zealand's professional accountability processes and removed error, or fault, from medical injury compensation eligibility criteria. Nevertheless, as the accountability processes themselves were largely unaffected by the reforms, it is likely that opposing views on the nature of New Zealand's regulatory environment persist today.

The purpose of this essay is to explore these contrasting views and, in the words of John Steinbeck, to write to:

"Try to understand each other. You can't hate men if you know them."³

The systems approach to patient safety

The notion of punishment has particular relevance for patient safety. Patients who are harmed by health care rightly demand that those responsible be held to account and even punished.^{4–6} However, most patient safety experts today advocate a systems approach to patient safety which assumes that doctors are fallible and bound to make mistakes that might harm patients and so recommends systems and processes be put in place to prevent mistakes and minimise harm.^{7–10} Such an approach will only thrive in an environment where doctors can share information about error and adverse events, and learn, without fear of punishment. Many patient safety experts therefore advocate a low-blame or non-punitive approach to mistakes and adverse events.^{7,11–14}

The Institute of Medicine in its landmark report *To err is human* concluded:

"Preventing errors and improving safety for patients requires a systems approach in order to modify the conditions that contribute to errors ...

The **ETHICS** column explores issues around practising ethically in primary health care and aims to encourage thoughtfulness about ethical dilemmas that we may face.

THIS ISSUE: Our guest ethicist and GP Katharine Wallis explores whether or not New Zealand's regulatory environment for doctors is punitive in nature.