



## How Does Pregabalin Help?

Pregabalin relieves pain and improves function and quality of life (QOL) for patients with chronic pain due to diabetic peripheral neuropathy (DPN) or postherpetic neuralgia (PHN). But few studies have looked at just why the pain relief and improved QOL go together. Is it because pregabalin has a direct independent effect on patient function and QOL, or are the improvements an indirect consequence of pain relief?

To find out, researchers from Eastern Virginia Medical School in Norfolk, Virginia; and Pfizer Inc, in New York, New York, reviewed data from 11 randomized, double-blind studies of pregabalin in 2,656 patients with neuropathic pain. The primary efficacy measure in each study was the mean pain score on an 11-point numeric scale, derived from patient pain diaries. Each study also used the 36-item Short Form Health Survey (SF-36), which includes 8 health status domains, such as general health, vitality, and social functioning; Patient Global Impression of Change (PGIC); and Daily Sleep Interference Scale (DSIS) scores, all as secondary efficacy measures.

Pregabalin treatment benefited patient function/QOL, with significant improvements in social functioning, role-emotional, mental health, bodily pain, vitality, and general health ( $P < .001$  for all). The PGIC scores also showed patient status/QOL was “much” or “very much” improved, compared with placebo. Patients in all the pregabalin arms also reported significantly improved sleep and pain scores. More patients on pregabalin achieved clinically meaningful improvement in pain ( $\geq 30\%$  decrease from baseline).

For the SF-36 domains that exhibited significant improvement in response to pregabalin treatment, the extent of improvement seemed related to the magnitude of pain relief. In general, patients on pregabalin who achieved at least moderate pain relief reported higher scores in the SF-36 domains. In fact, the researchers say, for all of the SF-36 domains, scores increased as mean pain scores decreased. Patients on pregabalin whose pain was relieved also had higher PGIC scores, which positively correlated with pain relief.

The researchers found a “substantial” direct treatment effect (18%-57% of the overall treatment effect) for

each SF-36 domain. A direct treatment effect accounted for most of the overall treatment effect in the role-emotional and mental health domains. In contrast, improvements in social functioning, global health, and vitality domain scores were largely due to indirect treatment effects, such as improvements in pain or sleep.

The greatest improvement in SF-36 domain scores was reported by patients who had the most pain relief. Indeed, the researchers say, those patients often reported SF-36 domain scores comparable with those of the general population.

This study is the first, according to the researchers, to examine whether treating patients with PHN and DPN with pregabalin has a direct effect on function/QOL distinct from its effects on pain and sleep. They estimated that this direct effect, which could not be explained by either pain relief or improvement in sleep, accounted for as much as 50% (depending on the specific domain) of the overall treatment effects. ●

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