

Re: Off label usage of medicine

Source: <http://sci.tech-archive.net/Archive/sci.med/2005-01/1643.html>

zwalanga_at_yahoo.com

Date: 01/20/05

Date: 19 Jan 2005 23:15:35 -0800

"I have had to make decisions about giving patients drugs for potentially fatal illnesses on too little information."

I think we want the same thing David. Thanks for your courtesy to me.
Zee

David Rind wrote:

> *zwalanga@yahoo.com* wrote:

> > : "*And sometimes, even when there is only weak evidence and no FDA*

> > *approval...etc...*"

> >

> > *It brings a tear to one's eye it does David. Your dedication to*

> > *democracy. Have you thought of writing ad copy me boyo?*

>

> *No, but I have had to make decisions about giving patients drugs for*

> *potentially fatal illnesses on too little information. Sometimes*

> *later*

> *information showed the decision to have been right and other times*

> *wrong. I remember begging drug companies for protease inhibitors well*

> *before they were approved by the FDA. I'm not sure why you think it's*

> *shilling for the drug companies to recognize that such decisions have*

> *to*

> *be made.*

>

> > <http://www.citizen.org/eletter/articles/neurontin.htm>

> > *Zee*

> >

> > *{and what was that David, about 27 "if's"?*

>

> *I honestly have no clue what you mean by that last sentence. As to*

> *the*

> *prior URL, the Public Citizen letter is deceptive in that it implies*

> *that there is no evidence that Neurontin works for any of these 11*

> *indications. That is just untrue. As an example (sticking with*

diabetic

> *neuropathy*):

>

> -----

> *TI – Gabapentin for the symptomatic treatment of painful neuropathy*
in

> *patients with diabetes mellitus: a randomized controlled trial.*

> *AU – Backonja M; Beydoun A; Edwards KR; Schwartz SL; Fonseca V; Hes*
M;

> *LaMoreaux L; Garofalo E*

> *SO – JAMA 1998 Dec 2;280(21):1831–6.*

>

> *CONTEXT: Pain is the most disturbing symptom of diabetic peripheral*
> *neuropathy. As many as 45% of patients with diabetes mellitus develop*

> *peripheral neuropathies. OBJECTIVE: To evaluate the effect of*
gabapentin

> *monotherapy on pain associated with diabetic peripheral neuropathy.*

> *DESIGN: Randomized, double-blind, placebo-controlled, 8-week trial*
> *conducted between July 1996 and March 1997. SETTING: Outpatient*
clinics

> *at 20 sites. PATIENTS: The 165 patients enrolled had a 1- to 5-year*

> *history of pain attributed to diabetic neuropathy and a minimum 40-mm*

> *pain score on the Short-Form McGill Pain Questionnaire visual*
analogue

> *scale. INTERVENTION: Gabapentin (titrated from 900 to 3600 mg/d or*

> *maximum tolerated dosage) or placebo. MAIN OUTCOME MEASURES: The*
primary

> *efficacy measure was daily pain severity as measured on an 11-point*

> *Likert scale (0, no pain; 10, worst possible pain). Secondary*

measures

> *included sleep interference scores, the Short-Form McGill Pain*

> *Questionnaire scores, Patient Global Impression of Change and*
Clinical

> *Global Impression of Change, the Short Form-36 Quality of Life*

> *Questionnaire scores, and the Profile of Mood States results.*

RESULTS:

> *Eighty-four patients received gabapentin and 70 (83%) completed the*

> *study; 81 received placebo and 65 (80%) completed the study. By*

> *intent-to-treat analysis, gabapentin-treated patients' mean daily*
pain

> *score at the study end point (baseline, 6.4; end point, 3.9; n = 82)*

was

> *significantly lower (P<.001) compared with the placebo-treated*
patients'

> *end-point score (baseline, 6.5; end point, 5.1; n = 80). All*

secondary

> *outcome measures of pain were significantly better in the gabapentin*

> *group than in the placebo group. Additional statistically significant*

- > differences favoring gabapentin treatment were observed in measures of
- > quality of life (Short Form-36 Quality of Life Questionnaire and Profile
- > of Mood States). Adverse events experienced significantly more
- > frequently in the gabapentin group were dizziness (20 [24%] in the
- > gabapentin group vs 4 [4.9%] in the control group; $P < .001$) and
- > somnolence (19 [23%] in the gabapentin group vs 5 [6%] in the control

- > group; $P = .003$). Confusion was also more frequent in the gabapentin
- > group (7 [8%] vs 1 [1.2%]; $P = .06$). CONCLUSION: Gabapentin monotherapy
- > appears to be efficacious for the treatment of pain and sleep
- > interference associated with diabetic peripheral neuropathy and exhibits
- > positive effects on mood and quality of life.
- > -----
- >
- > Pretending that data like these don't exist just because it wasn't
- > worthwhile for the manufacturer to apply to the FDA for an added
- > indication is just silly. Neurontin may not be worth its side effects

- > when used for diabetic neuropathy, but there is good evidence that it
- > relieves pain.
- >
- > --
- > David Rind
- > drind@caregroup.harvard.edu