PROJECT INFORMATION

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Comparing Four Medicines to Treat Pain from Cryptogenic Sensory Polyneuropathy (CSPN) -- The PAIN-CONTRoLS Study

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Organization

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What was the research about?

Cryptogenic sensory polyneuropathy, or CSPN, is a health problem that causes pain, numbness, and tingling. Pain is one of the worst symptoms of CSPN. Doctors can prescribe different medicines to treat CSPN pain, but few studies have compared how well these medicines work.

In this study, the research team compared four pain medicines for patients with CSPN: nortriptyline, duloxetine, pregabalin, and mexiletine. The team looked at how beneficial the medicines were by seeing if patients

- Reported that pain was 50 percent less than before taking the medicine
- Kept taking the medicine
- Avoided side effects

What were the results?

Based on pain reduction and patients being able to keep taking the medicine, nortriptyline and duloxetine had the highest benefit, followed by pregabalin and mexiletine.

Of the patients taking nortriptyline,

- 25 percent had pain reduced by half
- 38 percent stopped taking it

- 56 percent had side effects

Of the patients taking duloxetine,

- 23 percent had pain reduced by half
- 37 percent stopped taking it
- 47 percent had side effects

Of the patients taking pregabalin,

- 15 percent had pain reduced by half
- 43 percent stopped taking it
- 40 percent had side effects

Of the patients taking mexiletine,

- 20 percent had pain reduced by half
- 58 percent stopped taking it
- 39 percent had side effects

Patients taking mexiletine reported the least fatigue and the lowest amount that pain interfered in their lives. All four medicines improved patients' physical and mental health but didn't change how much pain interfered with their sleep.

Who was in the study?

The study included 402 patients with CSPN receiving care at one of 40 clinics across the United States. Of these, 85 percent were white, 7 percent were black, 4 percent were Asian, 4 percent were other or unknown races; 6 percent were Hispanic. The average age was 60, and 53 percent were men.

What did the research team do?

The research team assigned patients by chance to take one of the four medicines. Patients filled out surveys at the start of the study and again one, two, and three months later. The research team scored each medicine on its overall benefit. Higher scores meant a medicine worked better to decrease pain and fewer patients stopped taking it.

Patients with CSPN, caregivers of patients with CSPN, and members of a national neuropathy advocacy group helped with the study design. CSPN patients helped make sure the research focused on what was most important to patients. They also gave input on how to help patients stay in the study.

What were the limits of the study?

The research team scored medicines as less beneficial if a patient stopped taking them for any reason. The main reasons that patients stopped taking pregabalin was because it cost much more than the other medicines. Scores might have been different if the team separated out reasons for not taking a medicine. Also, the team only considered a medicine beneficial if it reduced pain by half. The medicines may have helped patients even when they didn't reduce pain by that much.

Future research could use a different way to measure how well the medicines lower pain. Researchers could also account for differences in the cost of medicines.

How can people use the results?

Patients and doctors can use these results when considering how to treat pain in patients with CSPN.

To learn more about this project, visit www.pcori.org/Barohn212.