

Key Points

1. Central neuropathic pain affects up to 40% of patients after spinal cord injury
2. While the exact prevalence of neuropathic pain with SM is not known, it is likely at least 40%
3. Neuropathic pain is not well understood and very difficult to treat
4. Randomized, controlled, double-blind study looked at the effectiveness of pregabalin versus a placebo in a group of SCI patients suffering from central pain
5. Patients were assigned randomly to receive either pregabalin or a placebo for 12 weeks and pain, sleep, anxiety, and depression were assessed regularly
6. Found that pregabalin significantly reduced pain, improved sleep, and lowered anxiety versus the placebo
7. 56% of pregabalin group reported they improved at the end of the treatment cycle
8. However, most pregabalin users reported mild to moderate side effects such as sleepiness, dizziness, and lack of energy
9. If suffering from neuropathic pain due to a syrinx, might want to talk with doctor about pregabalin

Definitions

central nervous system - the brain and spinal cord

central pain - pain due to damage to the central nervous system

double blind - clinical trial in which neither the patients nor the physicians know whether a given patient is receiving a treatment or a placebo

gabapentin - drug used to treat neuropathic pain; Neurontin

Pregabalin Effective In Treating Neuropathic Pain

January 31, 2007 -- Much of the research which is published on Chiari and syringomyelia is not considered scientifically rigorous. In fact, the research tends to be dominated by descriptive case studies and retrospective chart reviews on series of patients. This is not to say the published research is not valuable - it certainly is - but within the scientific and medical community much (but certainly not all) of the Chiari research is considered weak methodologically, which makes interpreting that research more difficult.

However, in a recent issue of the journal *Neurology*, a methodologically rigorous study was published by an Australian researcher (and scientists from Pfizer) which found that the drug pregabalin was effective in treating neuropathic pain due to spinal cord injury.

The study was a randomized, controlled, double-blind trial, which is considered the best type of study for evaluating the effectiveness of a drug or treatment. Randomized means that the patients involved in the study were randomly divided into groups; controlled means that the drug was compared against a placebo control; and double-blind means that neither the study participants nor the doctors running the trial knew who was receiving the drug and who was receiving the fake pills (placebo).

Neuropathic pain, or pain due to nerve damage, is a serious problem for syringomyelia patients. While it is not known precisely what percent of syringomyelia patients suffer from neuropathic pain, it is estimated that forty percent of people with traumatic spinal cord injuries develop neuropathic pain. It is likely that the percent is at least that high among syringomyelia patients.

Pain due to a syrinx or spinal cord injury is sometimes referred to as central pain, because it is due to a lesion of the central nervous system. Other types of neuropathic pain, such as due to diabetes or shingles, arise from damage to the peripheral nerve fibers and are thus referred to as peripheral neuropathic pain.

Based on previous research which showed that pregabalin was effective in treating peripheral neuropathic pain, this research group decided to examine whether the drug was also effective in treating central neuropathic pain due to spinal cord injury.

For their study, the researchers recruited adult spinal cord injured patients from several institutions throughout Australia. To participate, patients had to be at least 18 years old, suffer from chronic central neuropathic pain due to the spinal cord injury, and score at least 40 on a simple pain scale from 0-100. While the patients were allowed to stay on some drugs, they had to stop using gabapentin (Neurontin) before starting the trial. It should be noted that pregabalin, marketed as Lyrica by Pfizer, is considered a successor drug to Neurontin. Pregabalin is believed to work by reducing the production of certain neurotransmitters which are thought to be involved in causing neuropathic pain.

Using these criteria, the researchers recruited more than 130 patients for the study, of which 75% had a spinal lesion, such as a syrinx, which was identifiable on MRI. In order to establish a pain level baseline and to track changes, the participants were asked to keep a pain and sleep diary starting one week prior to treatments. The patients were randomly divided into two groups, with one group receiving pregabalin, and the other receiving a placebo. In order to keep both the patients and doctors in the dark about who was in which group, the placebos were made to look, smell, and taste just like the pregabalin pills.

The study lasted 12 weeks and patients came in to the office several times over the course of the study. In addition to the pain diaries, the participants completed pain, anxiety, and depression surveys during their office visits.

At the end of the study, the researchers found that the pregabalin was effective in reducing pain as compared to the placebo (see Table 1). Specifically, on a scale from 0 - 10, the pain for the pregabalin group went from an average of 6.54 at the start of the study to 4.62 at the end. For comparison, the average pain of the placebo group only went from 6.73 to 6.27.

Another way to look at the effectiveness of the drug is that at the end of the study, only 16% of the pregabalin patients were suffering from severe pain compared to 43% of the placebo group. In addition to reducing pain, the pregabalin was effective in significantly improving sleep and reducing anxiety for those who were taking it. Interestingly however, it did not significantly influence depression symptoms.

While the pregabalin was effective in treating pain, those taking it did report side effects (see Table 2). Overall 96% of the pregabalin group reported adverse effects, but most were considered mild to moderate. The most common unwanted effects were excessive sleepiness, dizziness, swelling, and lack of energy. While the

neuropathic pain - pain due to nerve damage; often difficult to treat and can arise spontaneously

neurotransmitter - chemicals which transmit signals between nerve cells in the brain/spine

nociceptive pain - pain in response to something that should be painful

pain - an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

peripheral nervous system - all the nerves in the body that branch out from the spinal cord and carry signals to and from the body

placebo - an inactive pill which is used to compare the effectiveness of a medicine against

pregabalin - a medication which was developed to treat neuropathic pain

randomized controlled trial - type of rigorous scientific trial in which subjects are randomly assigned to receive either the treatment being studied or a placebo

cerebellar tonsils - portion of the cerebellum located at the bottom, so named because of their shape

cerebrospinal fluid (CSF) - clear liquid in the brain and spinal cord, acts as a shock absorber

Chiari malformation I - condition where the cerebellar tonsils are displaced out of the skull area into the spinal area, causing compression of brain tissue and disruption of CSF flow

Source

Siddall PJ, Cousins MJ, Otte A, Griesing T, Chambers R, Murphy TK. [Pregabalin in central neuropathic pain associated with spinal cord injury: a placebo-controlled trial.](#) Neurology. 2006 Nov 28;67(10):1792-800.

researchers classified these complaints as mild to moderate, they were bad enough that 21% of the participants discontinued using the drug. This compared to only 13% of the placebo group.

Despite the side effects, given the limited options available to treat neuropathic pain, those suffering may want to discuss pregabalin with their doctors.

[Ed. Note: *It should be pointed out that several of the authors of this study are employed by Pfizer and that the study was funded by Pfizer, the manufacturer of pregabalin. Having said this, Neurology, where this work was published, is a well-respected, peer-reviewed journal.*]

Table 1
Study Results, Pregabalin (69) vs Placebo(67)

	Pregabalin		Placebo		Sig?
	Start	End	Start	End	
Pain	6.54	4.62	6.73	6.27	Y
Sleep	4.22	2.79	4.98	4.71	Y
Anxiety	6.74	5.16	8.67	7.49	Y
Depress.	5.86	5.44	6.61	6.29	N

Note: Sig? refers to whether the difference between the pregabalin group and placebo group was statistically significant, meaning the result is not likely due to chance.

Table 2
Most Common Reported Side Effects In Pregabalin Group(70 subjects)

Side Effect	Number Effected
Extreme Sleepiness	29
Dizziness	17
Edema/swelling	14
Lack of Energy	11
Dry Mouth	11
Constipation	9
Amnesia	7

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