

Vigabatrin for Infantile Spasms

Joyce A. Cramer

President, Epilepsy Therapy Project

A nonprofit 501-c-3 organization

Associate Research Scientist, Yale Univ School of Medicine





- Formed by parents of children living with uncontrolled seizures together with their doctor.
- Our Mission:
To advance new therapies for people living with epilepsy

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NEW Research Articles:
Cognitive Improvement Makes the List as Common Treatment Goal for Parents of Children with Intractable Epilepsy

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Does Treatment Aggressiveness Affect the Prognosis of Refractory Status Epilepticus?

UPCOMING EVENTS

EPILEPSY NEWS

Mar 24, 2006
SCN1A-associated epilepsy is linked to a channel dysfunction

Mar 24, 2006
Depression treatment in coronary artery disease trial is announced

Mar 24, 2006
Clinical depression may be associated with higher risk of out-of-hospital cardiac arrest

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FEATURE ARTICLES



>2,000 US
children (3-12 months)
each year are
diagnosed with
Infantile
Spasms

Infantile spasms

- Infantile spasms vary in clinical manifestations:
 - brief head nods, violent flexion of the trunk, arms, and legs. Most patients have more than one seizure type.
 - Frequently occur in clusters (with as many as 150 seizures), with a crescendo of severity.
- Prognosis is dependent on the underlying causes of the seizures.
 - Infantile spasms are frequently associated with developmental delay.
 - The intellectual prognosis is generally poor because many babies have neurological impairment prior to the onset of spasms. (NINDS)

A typical story:

- *"At first I thought Chris was just having the little body jerks when he was moved or startled, like my other children had when they were infants. But then I knew something was wrong. The jerks became more violent, and his tiny body was thrust forward and his arms flew apart. They only lasted a few seconds but started to occur in groups lasting a few minutes. It was so hard to see such a young baby having these things."* G. Holmes MD

» <http://my.epilepsy.com/node/88>

ACTH Treatment

- Treatment with corticosteroids such as ACTH and prednisone is standard, despite the risk of serious side effects.
 - When used in the gel form (which is given by injection), it is long-acting, so it can be given once or twice a day. Parents are taught how to give the injection so that the child can continue to live at home while receiving treatment. Injections are usually given daily for about 6 weeks.
 - Potential side effects of ACTH are irritability, increased appetite and weight gain, high blood pressure, low potassium in the blood, and high blood sugar. These side effects will go away once the ACTH is stopped.
 - Other side effects are rare but more serious. These include infections, changes in mental status because of high blood pressure, and bleeding from the gastrointestinal system. The impact of these side effects can be lessened if parents are taught the early signs to look for in the child. A visiting nurse should check the child daily for the first week after the start of treatment, and twice a week thereafter. Blood pressure should be checked often. C. O'Dell MSN
 - <http://my.epilepsy.com/node/4330>

Vigabatrin & Infantile Spasms

- 1990s: several studies found that VGB was effective in treating infantile spasms (aka West syndrome), an unusual form of epilepsy that begins between 3 and 12 months of age.
- **Initial studies showed spasm-free rates of 48%; children responded within a few days.**
 - "Vigabatrin was effective in rapidly producing freedom from spasms for symptomatic-other etiologies and tuberous sclerosis-induced infantile spasms." R Elterman, 2006



FACTS

- Vigabatrin has been approved elsewhere in the world and used for more than 20 years for initial treatment of these serious cases of infantile spasms associated with tuberous sclerosis.
 - *~~ 80% of children with Tuberous Sclerosis have epilepsy;*
 - *1/3 experience catastrophic Infantile Spasms*



Risk-Benefit Ratio

- Vigabatrin may affect visual fields of children who receive the drug for long-term treatment.
- That effect has to be weighed against the drug's ability to stop seizures that can have devastating consequences for mental and physical development for children.

Parents' rights to make decisions

- “The decision to use vigabatrin for infantile spasms should be an informed consent by parents.
- We urge FDA to give parents a choice.



Epilepsy Therapy Project
supports approval of:

Vigabatrin for Infantile Spasms