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Plain Language Summary of Publication

Long-term survival in children with drug-resistant epilepsy: plain language summary of a comparison between medicine, vagus nerve stimulation, and cranial epilepsy surgery in the USA

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Where can I find the original article on which this summary is based?

You can read the original article 'Comparison of long-term survival with continued medical therapy, vagus nerve stimulation, and cranial epilepsy surgery in paediatric patients with drug-resistant epilepsy in the USA: an observational cohort study' published in *The Lancet Child & Adolescent Health* at: https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(23)00082-2/abstract.

Summary

What is this summary about?

This is a plain language summary of a study that used **real-world data** from more than 18,000 children with **epilepsy** who continued to have **seizures** despite trying at least two types of **antiseizure medicine** (called drug-resistant epilepsy). The study looked at how three different types of treatments are associated with **survival** in children treated with (1) antiseizure medicine alone, (2) **vagus nerve stimulation (VNS) therapy** plus antiseizure medicine, and (3) **cranial epilepsy surgery** plus antiseizure medicine.

How to say (download PDF and double click sound icon to play sound)…

- **Cranial epilepsy surgery:** cray-nee-uhl eh-puh-lep-see sur-jer-ee
- **Seizure:** see-zher
- **Vagus nerve stimulation:** vay-guhs nurv stim-yuh-lay-shun

Real-world data: Information about how treatments work, collected from doctor visits, medical records, and patient experiences.

Epilepsy: A condition that causes seizures to happen again and again.

There are different types of epilepsy such as focal (or partial epilepsy, in which seizure activity starts from one part of the brain) or generalized epilepsy (when seizure activity is spread out across the brain).

Seizures: Episodes caused by an overload of electrical signals in the brain that may affect how a person appears or acts.

Antiseizure medicine: Medicine to treat seizures.

Survival: Continuing to live after being diagnosed with a medical condition or after receiving a related treatment.

Vagus nerve stimulation (VNS) therapy system: A small device placed under the skin in the chest and connected to the left vagus nerve, which carries signals between the brain, heart, and digestive system. The VNS device sends a mild electrical signal through the vagus nerve to the brain to eliminate, reduce, or shorten seizure activity.

Cranial epilepsy surgery: A brain surgery during which doctors temporarily open the skull and remove, disconnect, or destroy the part of the brain causing seizures. After surgery, the skull and skin are closed.

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What were the results?

- This was the first large study to study children with drug-resistant epilepsy over time to compare how different treatments were associated with their chances of surviving with epilepsy.
- Treatment with cranial epilepsy surgery plus antiseizure medicine and VNS plus antiseizure medicine were associated with higher survival than treatment with antiseizure medicine alone.
- Children from racial and ethnic minority groups or those without private insurance may have had less access to the epilepsy treatments associated with higher survival.
- A team-based healthcare provider approach that carefully reviews and combines different treatment options is important to improve care for patients with epilepsy.
- These findings can help healthcare providers and caregivers make better-informed treatment decisions when treating drug-resistant epilepsy in children.

What do the results mean?

This large study was the first to show that over 10 years, children with drug-resistant epilepsy who had cranial epilepsy surgery had a higher survival rate than those who did not. The study also found that over the same 10-year period, children who received VNS therapy had a higher survival rate than those treated with antiseizure medicine alone.

What is the purpose of this plain language summary?

This plain language summary has been prepared to help you understand the findings from recent research.

The results of this study may differ from those of other studies. Healthcare providers should make treatment decisions based on all the available evidence, not just on the results of one study.

The vagus nerve stimulation device is approved for use in the United States by the Food and Drug Administration as an adjunctive (add-on) therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory (resistant) to antiseizure medications.

Who should read this article?

This summary may be helpful for people who have drug-resistant epilepsy, or for parents, caregivers, family, and friends of children with drug-resistant epilepsy. This plain language summary may also be helpful for healthcare providers involved in diagnosing, treating, and caring for children with drug-resistant epilepsy, especially in discussing treatment options. **Patient advocacy groups** may also find this information helpful for educating caregivers and the people that they support.

Who sponsored the study?

There were no industry **sponsors** for this study.

This plain language summary publication was funded by LivaNova, PLC (London, United Kingdom). The funders had no role in the study design, data collection and analysis, or preparation of the plain language summary. The authors had full control of this plain language summary and provided their final approval of all content.

Patient advocacy groups: Organizations that provide support for people with a specific medical condition and their families.
Sponsor: A company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information from the study.

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Why was this study performed?

About 3.4 million people in the United States have epilepsy. People with epilepsy have seizures caused by abnormal electrical activity in the brain. Epilepsy is more common in children than adults. Around 1 in every 100 children have epilepsy.

People with epilepsy have a higher chance of dying than people of the same age without epilepsy. Children with epilepsy have an even higher risk of dying than adults with epilepsy. So, it is important to look at how different treatments for epilepsy may be associated with higher chances of remaining alive over time (higher survival).

Most people with epilepsy take medicine to help treat their seizures, but sometimes these medications do not control seizures. This is called drug-resistant epilepsy.

What is drug-resistant epilepsy?

When a child has drug-resistant epilepsy, they have tried at least two different antiseizure medicines but are still having seizures.

Of all the children who have epilepsy, about 2 out of 10 have drug-resistant epilepsy

How can we treat drug-resistant epilepsy?

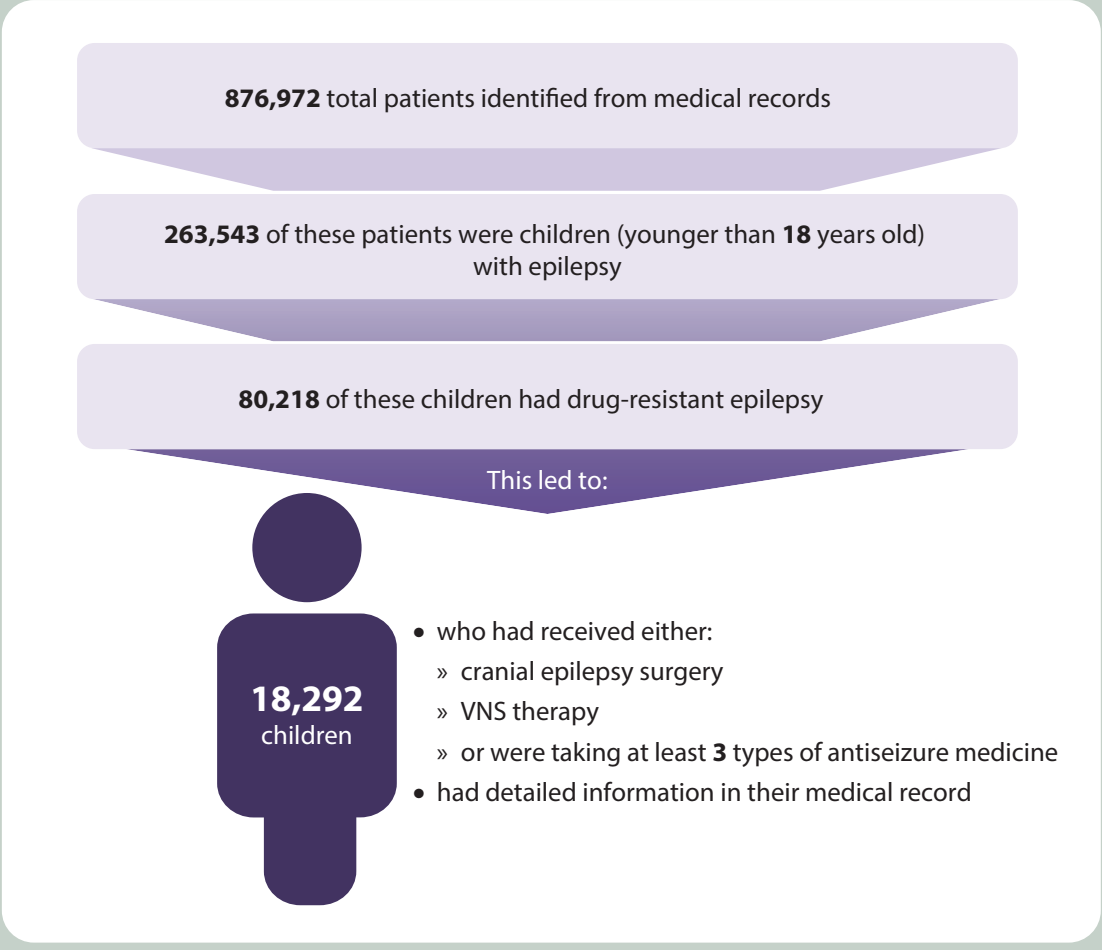
Children with drug-resistant epilepsy have a few treatment options when medicine cannot control their seizures, including but not limited to the following two approaches.

- Vagus nerve stimulation (VNS) therapy consists of a device that is placed into the body during a short surgery.
  - » The VNS device sends mild signals through the left vagus nerve to the brain to help reduce the volume and severity of seizures.
- Cranial epilepsy surgery can help manage seizures with the removal or alteration of certain parts of the brain that are associated with causing seizures.

There are not enough studies on how treatments for children with drug-resistant epilepsy may impact how long they live, so the researchers in this study wanted to learn more.

How was this study carried out?

The researchers used a multistep process (an approach in which tasks are completed in a certain order) to find medical records from the Children's Hospital Association Pediatric Health Information System, which includes more than 49 hospitals across the United States.



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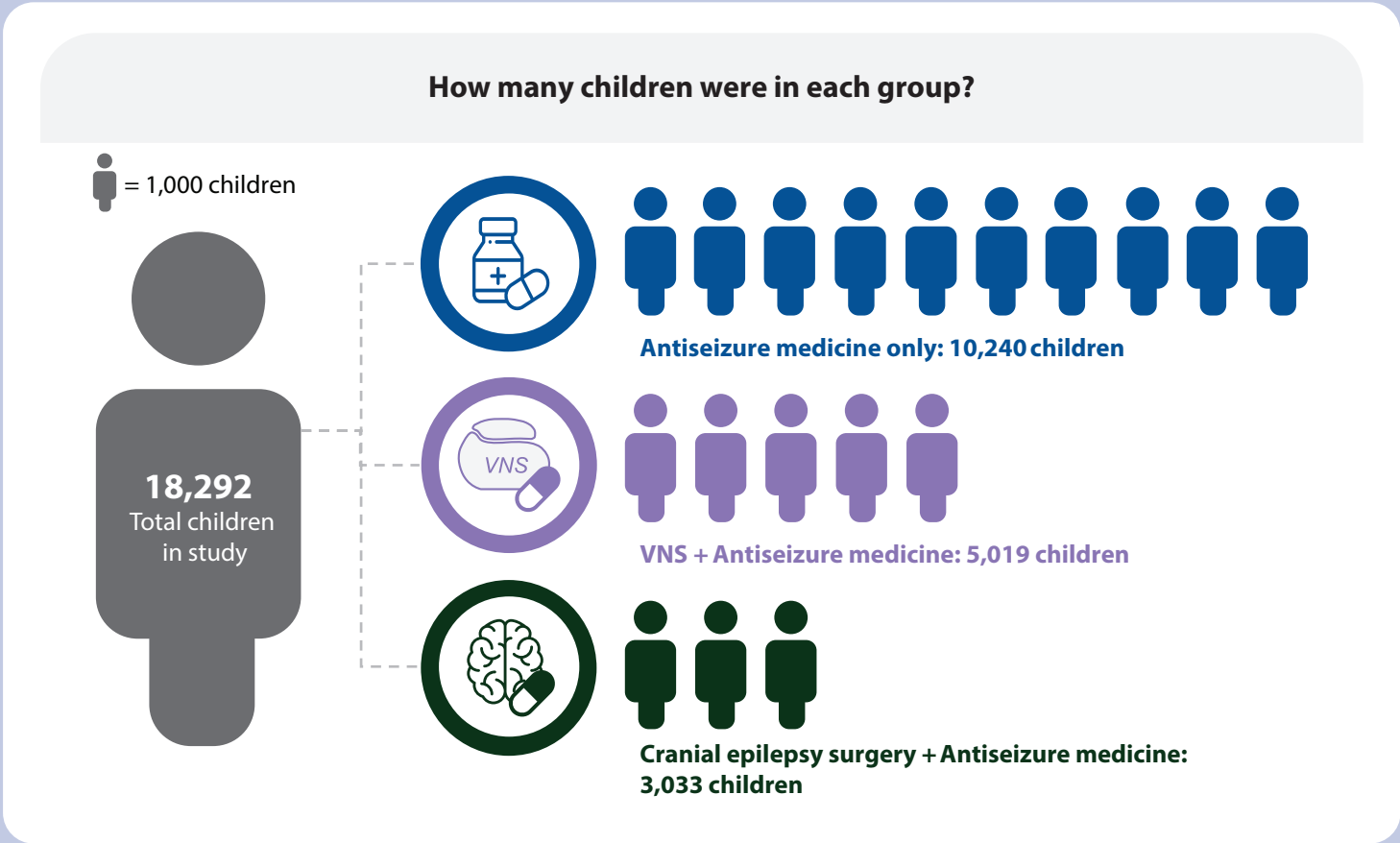
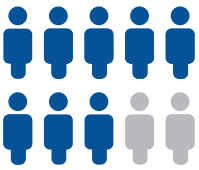
Who took part in this study?

The 18,292 children were put into three groups based on their treatments: antiseizure medicine only, vagus nerve stimulation (VNS) plus antiseizure medicine, or cranial epilepsy surgery plus antiseizure medicine.



What characteristics did the patients in the study have?



More than 80% of the children in the study were older than **4** years old

3 of every 4 children also had a long-term health condition

Almost 60% of the children were non-Hispanic White

About 50% of the children had Medicaid as their insurance, and **40% had private insurance**

About half the children were boys, and half were girls

Children were from the midwestern, northeastern, southern, and western parts of the United States

Children had a range of types of epilepsy diagnoses, including focal or partial, generalized epilepsy, or others

Compared with the children in the antiseizure medicine-only group, those in the other two groups were more likely to:

- Live in the midwestern or the western region of the United States
- Identify as non-Hispanic White
- Have either focal or partial epilepsy as their main epilepsy diagnosis
- Have private insurance

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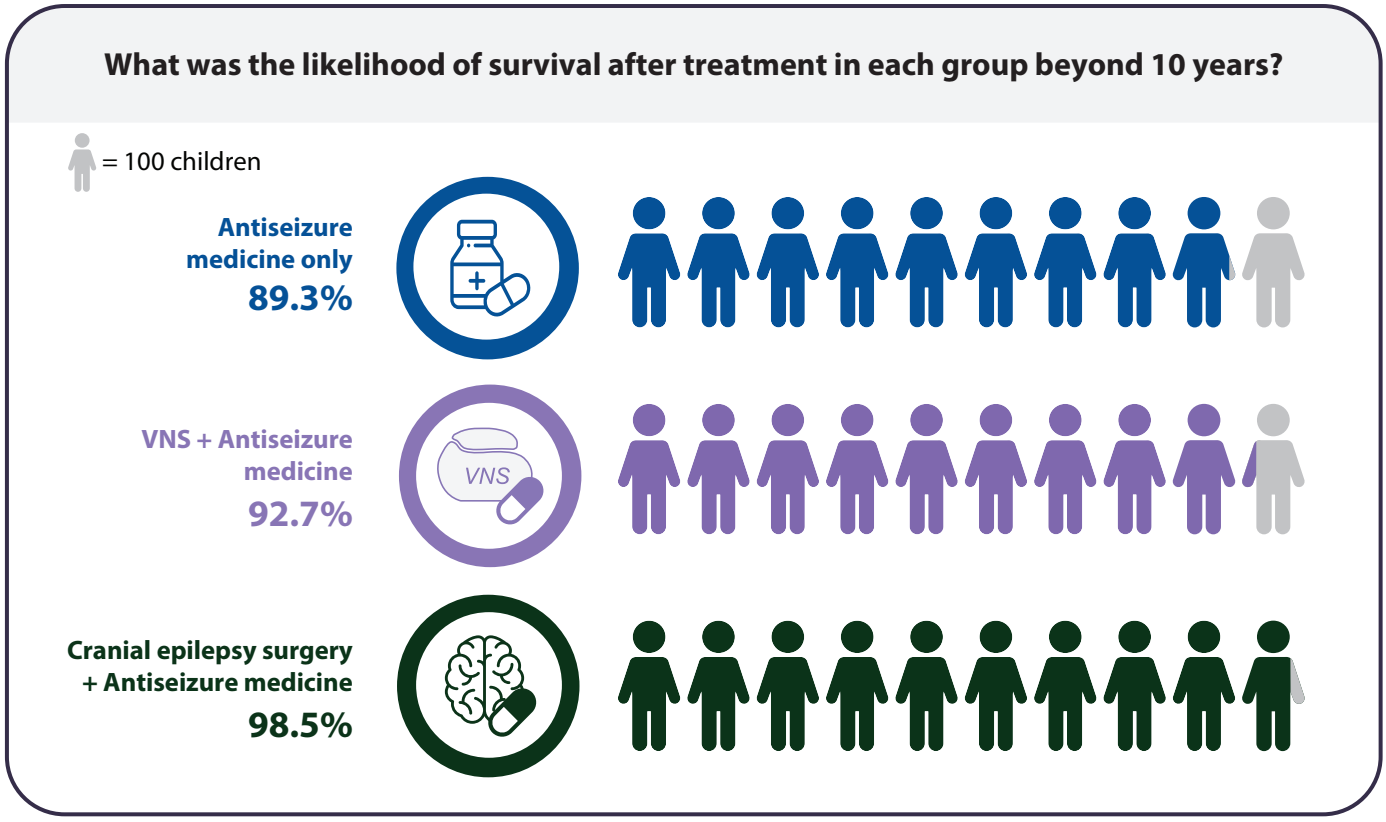
What did the results show?

What was the likelihood of survival after treatment in each group beyond 5 years?

- 95.5% for the children in the antiseizure medicine-only group.
- 96.8% for the children in the vagus nerve stimulation (VNS) plus antiseizure medicine group.
- 99.4% for the children in the cranial epilepsy surgery plus antiseizure medicine group.



- Of the 18,292 children in this study, those who combined cranial epilepsy surgery with antiseizure medicine had the highest survival rates (98.5% survival beyond 10 years), followed by VNS therapy plus antiseizure medicine (92.7%), while children who only took antiseizure medicine had the lowest survival rate (89.3%).

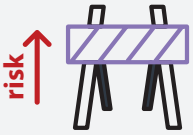
Did some patient characteristics impact overall risk of death?

The type of insurance children had did not have a big effect on their risk

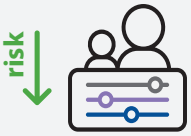
Boys and girls had a similar risk

Where children lived in the United States did not have a big effect on risk

Children with different races and ethnicities had a similar risk



Children with long term health problems had a higher risk



Children aged between **4–11** years had a lower risk compared with children under **4** years old

Compared with the children taking antiseizure medicine only, risk was lower in the VNS + antiseizure medicine group, and even lower in the cranial epilepsy surgery + antiseizure medicine group

- Children between ages 4 and 11 had a lower risk of death than those younger than 4, and children with long-term health conditions had a higher risk of death.
- Children with focal or partial epilepsy may have been associated with a greater chance of survival. However, more research is needed to confirm this finding.
- Differences (based on ethnicity and insurance type) were identified in the amount of access children had to cranial epilepsy surgery.

What do these results mean?

Overall, children who received cranial epilepsy surgery combined with antiseizure medicine had the highest survival rates, followed by those who were treated with vagus nerve stimulation (VNS) therapy plus antiseizure medicine. Taking antiseizure medicine alone resulted in the lowest survival rate.

Some patient characteristics may have affected children's risk of death or their access to cranial epilepsy surgery.

This study noted the importance of a multidisciplinary team approach that includes comprehensive evaluation and access to both medical therapies and cranial surgical treatment options for epilepsy.

Understanding the results of this study may help healthcare providers and caregivers to make informed decisions about the best treatment options for children with drug-resistant epilepsy.

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What are the limitations of this study?

As the data used in this study were from medical records, we cannot rule out the possibility that these records may have had mistakes or were missing information. Such possible errors or information gaps could miss some potential medical events (including death) that may have happened. In addition, the population of children that were studied came from across the United States, and it is possible that children from other countries may experience different treatment practices and/or show different patterns of responses to treatment.

Where can you find more information and support?

- The original article discussed in this summary entitled 'Comparison of long-term survival with continued medical therapy, vagus nerve stimulation, and cranial epilepsy surgery in paediatric patients with drug-resistant epilepsy in the USA: an observational cohort study' published in *The Lancet Child & Adolescent Health* is available at: https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(23)00082-2/abstract
- The full citation for the original article is: Zhang L, Hall M, Lam SK. Comparison of long-term survival with continued medical therapy, vagus nerve stimulation, and cranial epilepsy surgery in paediatric patients with drug-resistant epilepsy in the USA: an observational cohort study. *Lancet Child Adolesc Health*. 2023;7(7):455-462. doi:10.1016/S2352-4642(23)00082-2. PMID: 37276875

The data in this study were obtained from patients discharged from the hospital between January 1, 2004 and December 31, 2020.

Where can readers find more information on this study?

- Video interview with author Dr. Sandi Lam: https://www.neurologylive.com/view/how-surgical-interventions-improve-survival-rate-pediatric-epilepsy-sandi-lam
- Patient advocacy group post about this study: https://epilepsysurgeryalliance.org/2023/06/15/epilepsy-surgery-improves-survival/

General Educational resources and support

- Epilepsy Foundation: https://www.epilepsy.com/
- Pediatric Epilepsy Surgery Alliance: https://epilepsysurgeryalliance.org/
- Danny Did Foundation: https://www.dannydid.org/

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Disclosure statement

Lu Zhang and Matt Hall declare no competing interests. Monika Jones serves as the founder and executive director of the Pediatric Epilepsy Surgery Alliance. Tom Stanton serves as the president of the Danny Did Foundation. Sandi K Lam serves as a consultant and/or advisor for BrainLab, Encoded Therapeutics, Jaguar Therapeutics, LivaNova, Ovid Therapeutics, and Synergia; as a scientific advisory board member for CURE Epilepsy; and as a board member for the Pediatric Epilepsy Surgery Alliance. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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