American Association of Neurological Surgeons
Congress of Neurological Surgeons
AANS/CNS Section on Pediatric Neurological Surgery

Position Statement

on

Intracranial Neuromodulation for Drug-Resistant Epilepsy in Pediatric Patients

Background

It is estimated that approximately 1% of the global pediatric population, or 11 million children and adolescents worldwide, suffer from epilepsy.[1,2] Thirty percent of these patients experience drug-resistant epilepsy (DRE),[3] rendering them candidates for surgical intervention.[4,5] Given the significant increase in premature death that accompanies poorly controlled epilepsy,[6,7] as well as the detrimental impact that DRE has on pediatric brain development and neuropsychological and cognitive outcomes,[8] it is imperative that DRE is recognized and treated as early as possible in this vulnerable population.[9–11]

Position Statement

Government, private payers and health systems should support the use of intracranial neuromodulation devices for patients, regardless of their age, in cases deemed appropriate by the patient's multidisciplinary treatment team. An ever-expanding body of literature demonstrates these devices are not "investigational," and the use of these devices offers long-term cost savings for patients and payors alike. The vulnerability of the pediatric brain to acute disruptions and long-term injury posed by epileptic activity demands urgent and early attention. Intracranial neuromodulation offers tens of thousands of patients and their brains the opportunity to grow and develop without the devastating impact of uncontrolled epilepsy.

Rationale

The definition of DRE in pediatric patients is no different than in the adult population.[12] While many patients with DRE qualify for resective surgery, which offers a potential cure via ablation of a defined epileptogenic zone, a significant proportion suffer from more diffuse pathologies or syndromes not amenable to a curative approach or have seizures arising from eloquent areas that cannot be removed without causing substantial functional deficit.[4,5] Neuromodulation thus plays an important role in the epilepsy surgery armamentarium, offering substantial seizure reduction that often exceeds that expected with subsequent medication trials. Vagus nerve stimulation (VNS) — first approved by the Food and Drug Administration (FDA) in 1997 — obtained extended FDA approval for patients with DRE above the age of 4 years in 2017. This therapy provides an estimated 50% reduction in seizures in the majority of DRE patients,[13,14] including those with genetic etiologies.[14]

The advent of intracranial neuromodulation has substantially changed the DRE treatment landscape. Since the FDA approval of responsive neurostimulation (RNS) in 2013 and deep brain stimulation (DBS) in 2018 for patients with DRE older than 18 years, thousands of patients have safely

undergone intracranial neuromodulation surgery, with an overall median seizure reduction of up to 75% at seven-year follow-up for DBS and nine-year follow-up for RNS.[13,15] Compared to VNS, DBS and RNS thus represent significant progress in the treatment of DRE. Incredibly, these are patients who would otherwise have no alternative treatment options and many who have already received a VNS.[16] Patients with lesions in the eloquent cortex,[17] genetic epilepsies,[18,19] developmental and epileptic encephalopathies (DEE) like Lennox-Gastaut Syndrome (LGS),[15,20–22] multifocal seizure onsets or bitemporal epilepsy now face the possibility of dramatic seizure reduction via intracranial neuromodulation. The impact on their quality of life, cognition, and longevity is equally dramatic,[23–25] and includes profound decreases in rates of sudden unexpected death in epilepsy (SUDEP) for both DBS and RNS.[26,27]

Medically managed DRE is more expensive than surgically managed DRE. Poorly controlled epilepsy is estimated to surpass $20,000 per admission,[28,29] and although epilepsy surgery carries a high up-front cost, numerous analyses have demonstrated this to be offset by the long-term savings that improved seizure control provides.[28,30–32] Intracranial neuromodulation, which broadens the eligible population that could benefit from surgically managed seizure reduction, is thus expected to decrease health care costs for these patients further and as a whole.

Despite the current lack of FDA approval for these devices in patients under 18 years of age, the pediatric epilepsy community has long recognized the utility of intracranial neuromodulation for children and adolescents who suffer from unrelenting seizures.[33] The FDA approved the use of DBS in pediatric patients for severe dystonia in 2003,[34,35] and both RNS and DBS have been repeatedly demonstrated as safe and efficacious in the treatment of DRE, *independent of patient age*.[27,36–38] Additionally, there is evidence that in children with DRE already implanted with VNS, additional intracranial neuromodulation improves seizure control.[16]

Additional Endorsing Organizations

American Epilepsy Society
American Society of Pediatric Neurosurgeons

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