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Editorial

Epilepsy surgery for children with severe developmental delay: An ethical double jeopardy

1. Introduction

Double jeopardy in medical ethics was coined by John Harris to describe "those [innocent] people who have been disadvantaged by the indifferent nature of other people [who are] further disadvantaged by policy makers." [1]. This term was first applied to describe how basing treatment decisions on quality-adjusted life years (QALYs) is discriminatory for vulnerable populations who are already disabled by their illness. First, these patients are disadvantaged by their condition, and second, because of their lower baseline, lower priority is given to treatments that could improve their lives.

Double jeopardy is a common ethical dilemma that arises when a child with severe developmental delay is considered for epilepsy surgery. For example, in 1975, Davidson and Falconer [2,3] were selective with their criteria for surgical candidacy, and developmental delay was considered a contraindication to epilepsy surgery.

Children with epilepsy and severe developmental delay have functional disabilities that limit their learning, independence, and quality of life. Double jeopardy manifests when these factors further modify parents' and practitioners' decision-making regarding curative or palliative surgery. While global developmental delay (GDD) and intellectual disability affect about 2–3% of the population (with one-third of those affected demonstrating severe-to-profound level of impairment) [4], the rates in children with epilepsy are substantially higher. In many cases, the more severe the cognitive impairment, the less likely that seizure reduction will provide meaningful improvement in their quality of life. Conversely, GDD may be associated with a lesser likelihood of surgical success. The confluence of these factors, combined with the vulnerability of this patient population raises questions regarding resource allocation, caregiver expectations, and the risk–benefit ratio. Children with epilepsy and severe developmental delay also comprise a population of children who are unlikely to be involved in their own medical decision-making. When considering the provision of and access to care, the risk of double jeopardy must be recognized.

2. Patient considerations

Children with coincident epilepsy and developmental delay may be dichotomized into two cohorts: children who have secondary GDD due to epileptic encephalopathy (Type 1) and those who have coincident GDD and epilepsy without obvious causality (Type 2).

Uncontrolled epilepsy can lead to developmental delay, and early resolution of seizures can sometimes improve global development for Type 1 patients. Compared with children without epilepsy, children with refractory epilepsy or seizure disorders are 35–50% more likely to experience developmental delay [5,6]. The earlier the age of onset of intractable epilepsy, the higher the risk for development or cognitive delay, particularly if seizures occur more frequently [7].

Decisions regarding epilepsy surgery may be more controversial and value-laden if the etiology of the developmental delay is unknown (i.e., for Type 2 patients). Approximately a quarter of children with GDD have a genetic etiology, such as a chromosomal anomaly, submicroscopic deletions/duplications/rearrangements, or monogenic disorders [8]. Children with GDD or intellectual disability are at an increased risk for several comorbidities, including epilepsy or convulsive disorders, behavioral disorders, attention-deficits, psychiatric illness, and sensory impairments (i.e., vision and hearing) [9].

3. Surgery considerations

Likewise, surgical interventions may be dichotomized into procedures performed with the aim of seizure freedom (Type A procedures) and those performed with the intention of reducing seizure burden without cure (palliative intent; Type B procedures).

Type A procedures encompass resective surgery as well as hemispherectomy. Resective epilepsy surgery has proven to demonstrate a significant decrease of seizure frequency in 50 to 90% of patients [10–12]. Hemispherectomy or targeted resection of epileptic foci after careful presurgical analysis often will allow for complete seizure freedom [17–20]. Several studies report seizure freedom in 60–91% of children for temporal and 54–66% for extratemporal resections [12–16].

If preoperative assessments do not support a high likelihood of cure, children may still possibly benefit from palliative or Type B surgery, such as neuromodulation or callosotomy [21,22]. For example, children may benefit from vagus nerve stimulation (VNS) via improvements in their quality of life, arrest of cognitive decline, and improved mood and behavior [23–25]. Callosotomy in children, which is indicated solely for drop attacks also, has been reported to improve quality of life, behavior, and possibly intelligence [26,27].

It is often difficult to predict intellectual improvement after resective surgery or hemispherectomy, although it is suspected to correlate well with higher preoperative intelligence quotient (IQ), shorter epilepsy duration or earlier age of surgery, good seizure outcome, and decreased need for antiepileptic drugs [17,19,28–32]. Quantitative data are sparse, yet surgical improvement of seizure frequency is expected to contribute to the resumption of normal developmental progression after surgery if performed at a young age [12,31]. This would be expected to be more efficacious in Type A versus Type B procedures.

Importantly surgical complications may negate any potential benefit, particularly in children who are expected to achieve modest incremental gains. Given the heterogeneity of data regarding postoperative developmental or cognitive outcomes, it is important to evaluate

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the significance of minimal improvements for children who are already at a lower baseline. For example, epilepsy surgery may help a child regain the ability to smile, laugh, and recognize family members. These small expressions, formerly masked by ongoing seizures, may be viewed as a minor outcome to medical caregivers but can be of tremendous significance to the family. Double jeopardy manifests when practitioners or parents exhibit pessimism regarding the child with epilepsy and GDD and do not consider how meaningful even modest improvements in seizure control and neurocognitive function can be.

4. Ethical considerations

Double jeopardy occurs because many individuals and practitioners take on a utilitarian or consequentialist view of ethical decision-making. Utilitarian arguments based on theories offered by John Stuart Mill, Joshua Green, and Peter Singer will employ QALYs or equivalent scales to quantitatively judge the moral worth of a decision based on its overall benefit and costs to the patient and society [35,36]. All things being equal in a world of limited resources, two men of different ages may receive unequal healthcare simply because the younger man is expected to live longer and contribute more to society. Similarly, when comparing two children with epilepsy, the one with GDD may receive inadequate care; the benefit of seizure freedom may not be as pronounced for the child with GDD, and their comorbidity will constrain their future contributions to society as adults. Utilitarianists may argue that it is completely ethical, in the context of resource allocation, to prioritize patients with greater postoperative improvement. The child with GDD may benefit from epilepsy surgery, but the change may be modest and insignificant and perhaps, insufficient to justify the risk of surgical treatment, particularly if such treatment is increasingly invasive. In the hands of the utilitarians, children with GDD and epilepsy suffer a double jeopardy of being disadvantaged with GDD and further being deprioritized for surgery due to low expectations of postoperative development.

Such an argument fails to consider the experience of the child with GDD and epilepsy. With a developmental disability alone, a child can expect 1.5 times more doctor visits, 3.5 times more hospital-days, and a 2.5-fold increase in repeating a grade [37]. A meta-analysis of 21 studies demonstrated several risk factors that would decrease the quality of life for children with epilepsy: duration of epilepsy, seizure type, frequency, and severity, number of antiepileptic drugs, side effects of antiepileptic drugs, presence of a comorbidity, parental anxiety, and family socioeconomic status [38]. The diagnosis of epilepsy and the presence of intellectual disability are both independent factors that would reduce the health-related quality of life of children [39,40]. Palliative epilepsy surgery can serve to decrease seizure frequency and duration of epilepsy, both substantial risk factors related to the quality of life of these children [38,41]. Treatment decisions based on categorical contraindications fail to capture subjective experience with illness; physicians are often required to consider moral relativism and make treatments relative to social or personal circumstances.

Children may derive indirect benefit from a surgical procedure if the result of treatment includes better ease of care for their caregivers. Heavier caregiver burden is associated with higher number of antiepileptic drugs, poorer patient neuropsychological performance, and lower patient quality of life [42]. Parents of these children often need to acquire special education and social care for the specific needs of their children [43]. The personal effort and cost of raising these children can be tremendous. Financial concerns related to epilepsy treatment and anxiety for a child's vulnerability and future are common stressors for many caregivers [44,45]. Seizure reduction, whether in quantity or severity of seizures, can still have meaningful impact on a patient and their caregivers. If one were to conduct a comprehensive cost–benefit analysis of a treatment option, the benefits may be much more far-reaching than upon initial consideration.

On the other hand, some ethicists would turn to Kantian or deontological moral theory that would consider *rights and duties* [46]. The general categorical imperative of medicine and healthcare would support the treatment of patients with disabilities and disadvantages so that they can resume a greater quality of life. As simple examples: a woman with a broken leg would receive orthopedic surgery so she can resume walking; a teenager with attention deficit hyperactive disorder (ADHD) would accept a trial of a Ritalin so he can improve his attentiveness during school. Doctors have a fiducial obligation to treat all patients to the best of their abilities. Achieving equity despite inequality is a main component of the renewal of the World Health Organization's strategy of "Health for All" [47]. This was recently emphasized as a component of an ethical framework when considering access to epilepsy surgery [48]. Following this logic, children with epilepsy and GDD who are at a lower baseline possibly deserve greater attention and the allocation of more resources, including higher prioritization for surgical epilepsy treatment. Children with GDD are marginalized and dependent on their caregivers in a way similar to that of elderly patients who are relegated and isolated to nursing homes.

An additional ethical argument that complements double jeopardy would follow the principles established by John Rawls [35,49]. Rawls believed that allocation of resources on a societal scale should be considered behind a *veil of ignorance*, wherein the allocators themselves hypothetically do not know of their own abilities, disabilities, or position in society. The allocators must make these decisions knowing that they themselves can step in front of the veil and be any member of society and satisfied with their allocation. Behind such a veil, biases and prejudices are removed, and inequalities are justifiable only in so far as they operate to the advantage of the most disadvantaged members of society. This theory would also support the surgical treatment of children with epilepsy and GDD, given their disadvantaged state and at least provide them the opportunity for direct or indirect benefit.

5. Illustrative cases (Fig. 1)

5.1. Illustrative case 1: patient Type 1; procedure Type A

A 7-year old girl was diagnosed with medically-resistant epilepsy at the age of 3 years as a result of tuberous sclerosis. As she enters grade 2, she is demonstrating behavioral and cognitive difficulties. She is offered resective surgery to aim for seizure freedom.

This case may be the least controversial and least ethically dubious because most longitudinal studies support an improvement in cognitive and quality of life if seizure frequency can be reduced by surgery [32,34]. The overall quality of life can be expected to improve for both patients and their caregivers [50], best exemplified by Fiest et al. [51] who conducted a randomized control trial showing significantly more meaningful improvement after surgery compared with medical treatments, with a number needed to treat of two. The ability to compensate for surgical resection-induced deficits may depend on the integrity of other brain regions [54], and therefore, the postoperative risks for these patients may be lower than Type 2 patients undergoing Type A procedures. Deontological and utilitarian arguments would favor surgery with curative intent for this patient.

5.2. Illustrative case 2: patient Type 2; procedure Type B

A 7-year old girl with GDD was diagnosed with medically-resistant epilepsy at the age of 3 years. In the last two years, she has also been diagnosed with autism spectrum disorder, attention-deficit as well as learning disabilities and anxiety. Electrophysiological studies do not demonstrate a clear epileptogenic focus of her complex seizures that occur up to 150 times daily. Her family asks about surgery to decrease seizure frequency.

Postoperative cognitive outcomes are difficult to predict since intellectual disabilities correlate to diffuse morphologic brain damage and

	Patient Type 1 GDD secondary to epilepsy	**Patient Type 2** Coincident GDD & epilepsy without obvious causality
Surgery Type A Curative Surgery (e.g. Lesionectomy, hemispherectomy)	Low	Moderate
Surgery Type B Palliative Surgery (e.g. Vagus nerve stimulation, callosotomy)	Moderate	High

Fig. 1. Risk of double jeopardy, stratified by patient and procedure types.

increase the probability of multifocal epilepsy or diffuse epileptogenic regions. This patient would not be a candidate for resective surgery, but it is unclear also if palliative VNS or callosotomy will benefit her either [23–27,52,53].

Children with coincident delay and epilepsy are more likely to be neglected by initial utilitarian analysis as the postoperative cognitive benefits and improvement in quality of life are not clear. If seizures are not clearly the etiology of GDD, seizure freedom will not benefit this child as much as it would benefit a child with epilepsy without GDD or a child who has GDD, which is a result of epileptic encephalopathy. A policy of maximizing QALYs will disadvantage a child with a severe disability as the assessment of the change in a child's health status is limited, and the patient is very likely to face the bias of double jeopardy [35,55]. Despite the best surgical care, it is expected that these children will have an intrinsically lower ability to contribute to society.

By recognizing the risk of double jeopardy, physicians and parents have to make several value-laden decisions. Palliative epilepsy surgery can potentially decrease seizure frequency and that can still result in some improvement in the quality of life of patients and facilitate their care. Seizure reduction may also entail a reduction in antiepileptic medications and their associated side effects. The experience of the child with epilepsy must modify clinical decision-making and inform the preoperative discussion.

6. Conclusions

The goals of surgical treatments are to treat the disabled and help the infirmed. It is critical to recognize clinical decision-making biases against children with developmental delay and appreciate the risk of double jeopardy inherent to each presurgical consultation. Each child with epilepsy, irrespective of their developmental status, should have a comprehensive presurgical evaluation, the goal of which is to determine how the epilepsy surgery could contribute to their well-being and modify their experience with illness. To provide equity despite inequality, it is important to recognize the challenge of double jeopardy and assiduously investigate the etiology and causality of developmental delay. Only with due diligence can the epilepsy team ethically present the appropriate risks and benefits of surgery to parents and caregivers.

Conflict of interest statement

There are no conflicts of interest to disclose.

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