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Decision analysis of intracranial monitoring in non-lesional epilepsy

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ABSTRACT

Purpose: Up to one third of epilepsy patients develop pharmacoresistant seizures and many benefit from resective surgery. However, patients with non-lesional focal epilepsy often require intracranial monitoring to localize the seizure focus. Intracranial monitoring carries operative morbidity risk and does not always succeed in localizing the seizures, making the benefit of this approach less certain. We performed a decision analysis comparing three strategies for patients with non-lesional focal epilepsy: (1) intracranial monitoring, (2) vagal nerve stimulator (VNS) implantation and (3) medical management to determine which strategy maximizes the expected quality-adjusted life years (QALYs) for our base cases.
Method: We constructed two base cases using parameters reported in the medical literature: (1) a young, otherwise healthy patient and (2) an elderly, otherwise healthy patient. We constructed a decision tree comprising strategies for the treatment of non-lesional epilepsy and two clinical outcomes: seizure freedom and no seizure freedom. Sensitivity analyses of probabilities at each branch were guided by data from the medical literature to define decision thresholds across plausible parameter ranges.
Results: Intracranial monitoring maximizes the expected QALYs for both base cases. The sensitivity analyses provide estimates of the values of key variables, such as the surgical risk or the chance of localizing the focus, at which intracranial monitoring is no longer favored.
Conclusion: Intracranial monitoring is favored over VNS and medical management in young and elderly patients over a wide, clinically-relevant range of pertinent model variables such as the chance of localizing the seizure focus and the surgical morbidity rate.
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1. Introduction

Up to one third of patients with epilepsy develop medication-refractory epilepsy [1]. Surgery is often an effective treatment for these patients. Several studies, including a randomized controlled trial and a decision analysis [2,3], demonstrate the effectiveness of surgery in temporal lobe epilepsy. These patients have up to an 80% chance of post-operative seizure freedom. Similarly high rates of success are seen in lesional extratemporal epilepsy [4].

Patients without an MRI-evident structural lesion as the etiology for their epilepsy do not fare as well with surgery. These patients have reported post-operative seizure freedom rates between 30% and 40% [5,6]. For patients with non-lesional epilepsy, intracranial EEG monitoring is often necessary to localize the epileptogenic zone. However, intracranial monitoring comes with inherent surgical risks, including hemorrhage, CNS infections, stroke and death [7]. Furthermore, in a significant minority of patients, the epileptogenic focus can remain poorly localized even with extensive electrode coverage [8]. An important unresolved question is whether the population of epilepsy patients who are non-lesional and under consideration for intracranial EEG monitoring generally derives net benefit rather than harm from the extensive work-up and inherently invasive nature of intracranial monitoring necessary to determine candidacy for resective surgery.

Alternatives to intracranial monitoring include vagal nerve stimulator (VNS) implantation and further use of anti-seizure medications. These alternatives carry less upfront risk than intracranial monitoring but also have less chance of achieving seizure freedom, tending to result in seizure improvement instead. A comparison between the potential benefits and risks of these treatment options is necessary to optimize treatment protocols for patients with non-lesional epilepsy.

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A randomized controlled trial is the ideal methodology to address the question of whether the expected benefits of intracranial monitoring outweigh its expected risks for patients with non-lesional medication refractory epilepsy. However, the high cost and logistical difficulties of conducting an adequately powered randomized controlled trial are substantial. Decision analysis offers a viable alternative methodology for weighing the risks and benefits of various treatment options. In a decision analysis, the treatment options under consideration and the possible outcomes from each treatment are modeled as branches in a decision tree. Sensitivity analyses are then performed on parameters of interest to define the parameter range over which a specified treatment is favored. This allows for the "best" treatment option to be found (e.g. the option producing the highest quality of life or the lowest cost, depending on the metric used in the study) for each range of values of a parameter of interest. Base cases are constructed by inputting parameter values that apply to patients of a certain demographic, and the best treatment option for each base case is determined.

The present study comprises a decision analysis comparing three treatment strategies for patients with non-lesional medication refractory focal epilepsy who are under consideration for intracranial EEG monitoring: 1) intracranial monitoring with the intention of resective surgery, 2) VNS implantation and 3) continued medical management. The metric used to decide between the treatment strategies is the quality-adjusted life years.

2. Methods

2.1. Model structure

All modeling was conducted with TreeAge Pro HealthCare (Williamstown, MA). The decision analysis employs a decision tree. The first branch lists the decisions under consideration then proceeds through branch points that represent stochastic events such as the mortality from a surgery. The tree ends in the possible outcomes.

In this model we restrict attention exclusively to patients who are potential candidates for resective surgery after intracranial monitoring. The model thus begins at a decision node which branches into three treatment strategies: intracranial monitoring with the intention of resective epilepsy surgery, VNS implantation, and medical management. The potential complications include death and permanent morbidity from electrode implantation, resective surgery, or VNS placement. Potential outcomes include seizure freedom with or without morbidity, failure to achieve seizure freedom with or without morbidity, and death. While seizure improvement without seizure freedom is another potential outcome, a prior quality-of-life (QOL) study indicates that seizure improvement alone does not substantially improve QOL [9]. We therefore chose not to include this outcome in the model. The decision tree is illustrated in Fig. 1.

Medical management carries a low risk of permanent morbidity and death, so the possible outcomes from medical management are seizure freedom (without morbidity) and no seizure freedom (without morbidity). VNS may result in permanent morbidity; thus, seizure freedom and no seizure freedom, either with or without permanent morbidity, are possible outcomes from VNS.

Intracranial monitoring may lead to death with a low probability. In the likely event that the patient survives the electrode implantation procedure, morbidity may or may not result from the procedure. If the patient develops permanent morbidity it is assumed that they do not proceed to resective surgery and instead go on medical management. For patients that do not develop morbidity, their seizures are either localized or not localized. If intracranial monitoring fails to localize the seizures,

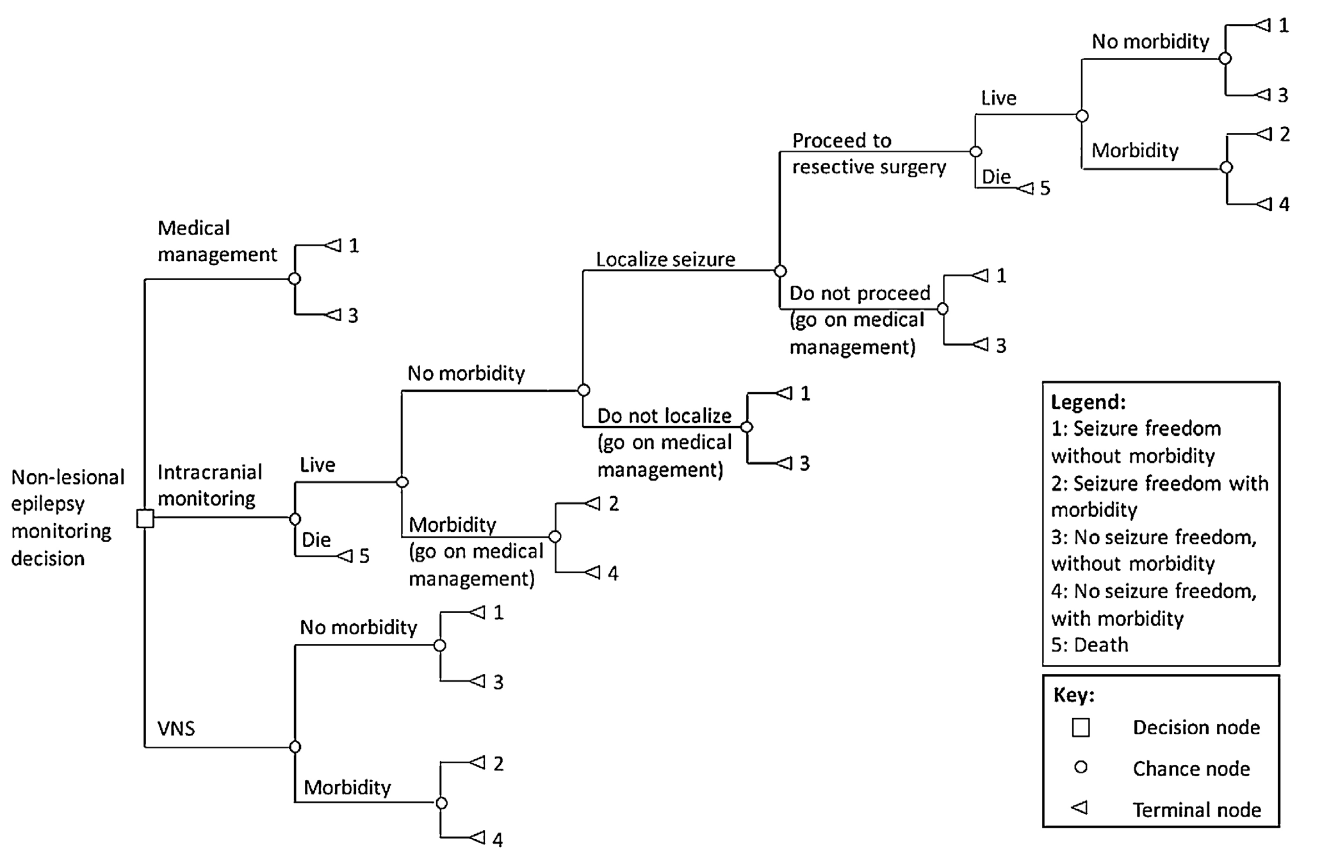

Fig. 1. Decision tree model. The possible outcomes are: (1) seizure freedom without morbidity, (2) seizure freedom with morbidity, (3) no seizure freedom, without morbidity, (4) no seizure freedom, with morbidity, or (5) death.

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