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Evidence-based methodology for obtaining commercial insurance coverage of stereotactic radiosurgery for intractable epilepsy

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ABSTRACT

Objectives: The coverage policies of many commercial insurers in the United States do not include coverage of stereotactic radiosurgery (SRS) for intractable epilepsy despite recent Level I evidence supporting its efficacy. We sought to assess the efficacy of an evidence-based methodology in obtaining coverage approval of SRS for intractable epilepsy.

Patients and Methods: The clinical policy guidelines from five of the largest United States commercial insurers were reviewed for their language regarding coverage of SRS for epilepsy. An evidence-based questionnaire was created for temporal lobe epilepsy and extratemporal lobe epilepsy based on recent evidence. Telephone interviewers of Insurers assessed the likelihood of SRS coverage for an epilepsy patient meeting the clinical inclusion criteria in the questionnaire. This likelihood was assessed numerically based on interviewee response (2 = yes, 1 = dependent on peer-to-peer, 0 = no).

Results: Of the five policy guidelines, none included literature more recent than 2017. For TLE, 3/5 insurance companies indicated likely SRS coverage; 2/5 indicated peer-to-peer discussion dependence for patients meeting questionnaire criteria for a score of 8/10. For extratemporal TLE, 2/5 companies indicated likely SRS coverage and 3/5 indicated peer-to-peer discussion dependence for a total score of 7/10.

Conclusion: Creation of an evidence-based methodology in approaching commercial insurers greatly increased the likelihood of SRS coverage for an indication (intractable epilepsy) widely perceived as investigational. These results should pave the way for epilepsy patients to receive coverage should they be appropriate SRS candidates.

1. Introduction

For nearly two decades, Level I evidence has demonstrated that for patients with temporal lobe epilepsy refractory to at least two antiepileptic drug trials, the likelihood of seizure freedom with continued medical therapy alone is less than 10%.[1] The randomized controlled trial by Wiebe et al. in 2001 established that anterior temporal lobectomy provided markedly superior one-year seizure freedom of 58% compared to 8% with continued medical management alone.[1] More recent nationwide analysis of anterior temporal lobectomy has demonstrated this operative procedure to produce low morbidity.[2]

However, for patients who either are not surgical candidates, or prefer noninvasive intervention, stereotactic radiosurgery (SRS) has emerged as a potential alternative for the treatment of intractable temporal lobe epilepsy (TLE), spurred initially by the success of SRS in treating epilepsy associated with cerebral arteriovenous malformations.[3] This resulted in pilot attempts at SRS in treating TLE utilizing a dose of 20 Gy; unfortunately, this dose remained inadequate to control TLE, with the persistent seizures resulting in fatal consequences.[4] In part due to this inadequate control, the SRS dose of 24 Gy was used for the Radiosurgery versus Open Surgery for mesial temporal lobe Epilepsy (ROSE) randomized multicenter clinical trial, resulting in a three-year seizure freedom (Engel Class I) rate of 52%.[5] While this rate failed to prove the noninferiority of SRS compared with anterior temporal lobectomy (78% three-year seizure freedom rate), for TLE patients who are not surgical candidates, SRS represents a treatment modality with proven seizure control superior to continued medical management alone.[1,5,6]

Unfortunately, despite the inclusion of intractable epilepsy as an appropriate indication for SRS in the American Society for Radi-

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ation Oncology (ASTRO) published model policies, recent work has indicated that the coverage policies of the largest publicly available commercial insurers in the United States do not include routine coverage of SRS for intractable epilepsy.[7] We sought to assess the efficacy of an evidence-based methodology in obtaining coverage approval of SRS for intractable epilepsy.

2. Materials and methods

The clinical policy guidelines from five of the largest publicly available commercial insurers in the United States (Aetna, Anthem, Cigna, Humana, United) were reviewed for their language regarding coverage of SRS for epilepsy. An evidence-based questionnaire was created from the ROSE trial inclusion criteria for TLE patients, and based on recent epilepsy surgery cohort studies for extratemporal epilepsy patients (Table 1). Insurers were subsequently contacted by telephone within the same month of policy guideline review and questionnaire creation (October 2019); radiation oncology medical directors were interviewed to assess the likelihood of SRS coverage for an epilepsy patient meeting the clinical inclusion criteria in the questionnaire. For TLE, criteria included: 1. Sufficient continuous video electroencephalography to determine a unilateral medial temporal seizure focus with MRI-concordant hippocampal sclerosis, 2. Wada test/functional MRI to lateralize language, 3. Minimum of three focal-onset seizures with impairment of consciousness over a three month period despite at least two antiepileptic medication trials, 4. Absence of neurologic deficits or visual deficits outside of seizure episodes, 5. Absence of psychiatric diagnoses, 6. Deemed a nonoperative candidate by a neurosurgeon (Table 1). For extratemporal epilepsy, criteria included: 1. Diagnosis of epilepsy established by a neurologist, 2. Persistent epilepsy despite more than one antiepileptic drug trial, 3. Proposed anatomic region to be targeted aligning with anatomy associated with seizure reduction in evidence-based literature, 4. Deemed an appropriate SRS candidate by radiation oncology and neurosurgery (Table 1). A score was derived to assess the likelihood of SRS coverage for TLE and extratemporal TLE based on interviewee response (2 = yes, 1 = dependent on individual MD discussion during peer-to-peer, 0 = no).

3. Results

Of the five policy guidelines, none had included the results of the ROSE trial despite it having been published more than 18 months prior to review. As a result, two deemed SRS for intractable epilepsy listed as investigational due to “insufficient evidence”, one failed to mention epilepsy as an indication for SRS, one cited a policy of all SRS epilepsy cases requiring medical review, and the fifth cited the lack of Level I evidence precluding the formation of guidelines. No guideline cited literature more recent than 2017.

For TLE, three of five insurance companies indicated SRS coverage was likely for patients meeting the questionnaire criteria, with the other two expressing coverage dependent on peer-to-peer discussion for a total score of 8/10. For extratemporal TLE, two insurance companies indicated likely SRS coverage with the remaining three recommending coverage dependent on peer-to-peer discussion for a total score of 7/10.

4. Discussion

The results from this study indicate the benefits of pursuing an evidence-based methodology in approaching insurance carriers, particularly in the instance of newer Level 1 evidentiary studies, which in this instance was universally excluded from the insurer policy guidelines. The positive response to questions derived from the ROSE study reaffirm the benefits of remaining up-to-date with

Table 1
Questionnaire used during assessment of insurance coverage for stereotactic radiosurgery (SRS) treatment of intractable epilepsy; any patient meeting all of these criteria is an optimal candidate and should never be denied SRS coverage.

Temporal Lobe Epilepsy	Yes/No
1. Has the patient had sufficient continuous video electroencephalography to determine a unilateral medial temporal seizure focus?	
2. Does the patient have magnetic resonance imaging (MRI) evidence of concordant unilateral hippocampal sclerosis without significant secondary cortical lesions?	
3. Has the patient had a Wada test or a functional MRI to lateralize language?	
4. Has the patient completed a standard battery of neuropsychological testing?	
5. Has the patient had at least 3 focal-onset seizures with impairment of consciousness over a 3 month period despite two or more antiepileptic medication trials?	
6. Has the patient had exclusion of supratentorial abnormalities by brain MRI?	
7. Does the patient have absence of neurological deficits outside of seizure episodes?	
8. Does the patient have absence of visual deficits outside of seizure episodes?	
9. Does the patient have absence of psychiatric diagnoses?	
10. If the patient has never had anterior temporal lobectomy, has the patient been deemed by Neurosurgery as a nonoperative candidate for anterior temporal lobectomy?	
Extratemporal Epilepsy	Yes/No
1. Does the patient have a diagnosis of epilepsy established by a Neurologist?	
2. Has the patient’s epilepsy persisted despite persisted despite more than one antiepileptic drug trial?	
3. Does the proposed anatomic region to be targeted align with anatomy associated with seizure reduction following focal treatment in evidence-based literature?	
4. Is there imaging evidence (i.e. MRI) of the anatomic region to be targeted correlating with the diagnosis of epilepsy?	
5. Has the patient been deemed an appropriate candidate for stereotactic radiosurgery by a Radiation Oncologist and a Neurosurgeon?	

practice-changing literature in advocating for optimal care for our patients. The results for extratemporal epilepsy coverage, inspired by recent anatomically-based studies indicating the piriform cortex as a potential anatomic target for surgical or SRS treatment of intractable epilepsy,[8,9] indicate the potential for hypothesis-driven SRS treatment of intractable epilepsy beyond the boundaries of the ROSE trial to be covered by insurance under appropriate conditions. Limitations to this study include its reliance on theoretical examples as opposed to actual patient cases, and the interview-based nature of the methodology.

In conclusion, creation of an evidence-based methodology in approaching commercial insurers greatly increased the likelihood of SRS coverage for an indication (intractable epilepsy) widely perceived as investigational. For TLE patients who are nonoperative candidates, the three-year seizure freedom rate of 52% provided by SRS in the ROSE trial far exceeds the 8% seizure freedom rate of continued medical management alone,[1,5] indicating that these patients should almost never be denied coverage of SRS in treatment of their intractable epilepsy. These results should provide a framework for these patients to receive coverage should they be appropriate candidates for SRS.

Statement of author contributions

Conception and design: McClelland; Data collection: McClelland, Verma; Data interpretation: McClelland, Verma; Manuscript writing: McClelland; Final approval of manuscript: McClelland, Verma.

Conflict of interest

None.

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