Special report: MEG and MSI for the purpose of presurgical localization of epileptic lesions - a challenge for technology evaluation
BlueCross BlueShield Association

Record Status
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Citation

Authors' objectives
The objective of this Special Report is to present the particular challenges that this diagnostic technology presents in terms of evaluating the evidence to determine its potential benefit. Without a thorough presentation of the manner in which MEG is used in the evaluation of patients, it is difficult to determine whether the technology is beneficial. Various problems such as ascertainment biases, patient dropouts, and imperfect reference standards crop up in the published studies evaluating MEG, making it more difficult to assess them. To some extent, these difficulties may be inherent in the clinical setting in which MEG is used.

Authors' conclusions
Assessment of diagnostic technologies used for the purpose of localizing surgical sites that may relieve seizures is fraught with difficulty. Fundamentally, the disease is not fully understood to the point that there is completely solid knowledge as to what factors result in a surgical cure. Surgical cures can occur in the context of a positive or negative noninvasive test of any kind. Surgical cure can occur when findings on the intracranial electroencephalogram (IC-EEG) are negative, but other imaging tests point to a region that may cause seizures. If it is understood that IC-EEG is a rather imperfect reference standard, then it is understandable that tests that have an imperfect correlation to IC-EEG may be viewed by some as providing equivalent or better information than IC-EEG, at times.

The diagnostic workup of patients includes consideration of IC-EEG, an invasive procedure that carries risks of complications. Many patients apparently drop out of the diagnostic workup before having this test, meaning that there is an inherent ascertainment bias in comparing this test to other possibly complementary or substitute tests. Studies that do not take this into account are difficult to evaluate, and studies may not be comparable due to differing unobserved patients. Evaluation of the correlations between IC-EEG and other tests is also made difficult by the inherent nonindependence of IC-EEG and the preceding workup.

By what standard, then, should a diagnostic technology such as MEG, when used to localize seizure locus, be held to in order to determine whether it is effective or not? Are randomized, controlled trials possible comparing ultimate outcomes of patients entering the diagnostic workup, one arm utilizing MEG and another arm not utilizing MEG? Are there epilepsy centers in the country that do not have or believe in MEG, that could enroll patients in an observational study comparing their outcomes to an otherwise similar epilepsy center that does utilize MEG? Given the difficulties of evaluating MEG strictly as a diagnostic test (due to ascertainment biases and lack of an independent reference standard), perhaps MEG needs to be viewed as part of the therapeutic process, in which the ultimate comparison is “MEG-guided surgical decision-making” versus “non-MEG-guided surgical decision-making.”

Lacking this type of true comparative information on health outcomes, is it possible to make a case for the effectiveness of MEG using data generated from clinical practice, essentially case series data? One study suggests that even with optimistic assumptions regarding the unobserved patients, it is likely that neither the sensitivity nor specificity of MEG is sufficiently high to bypass IC-EEG in patients either proceeding to surgery or stopping the workup. This would end the case for MEG if IC-EEG, despite its imperfections, were a mandatory part of the workup for seizure surgery. However, surgery can be successful without a positive IC-EEG in the experience of some
researchers and in some patients without IC-EEG at all.

The argument that MEG improves the diagnostic yield of IC-EEG is often made, but it is difficult to identify studies that can support this argument. Studies that compare IC-EEG to MEG do not inform this particular question. On the other hand, given the gravity of this particular situation, there are some possible arguments to be made on behalf of MEG. Given that current decisionmaking regarding who should receive surgery and what type of surgery is done with some uncertainty and lack of a true reference standard, an additional piece of information that is known to correlate with seizure focus could be arguably of some value in making difficult decisions. The diagnostic test is easy to perform and noninvasive. Also, IC-EEG and surgery are extremely invasive procedures that do not always provide diagnostic information. Information from MEG might influence a patient’s decision to undergo the risks of further testing or surgery if the outcome can be slightly better estimated. However, given that one possible outcome of use of MEG may result in avoidance of tests and procedures that may benefit the patient, it is not possible to rule out harm from use of the test. The net effect of the use of MEG on patient outcomes for this indication remains to be determined.

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