Epilepsy Research (2014) **108**, 775—781

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journal homepage: www.elsevier.com/locate/epilepsyres

The added clinical and economic value of diagnostic testing for epilepsy surgery

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Received 15 June 2013; received in revised form 22 January 2014; accepted 2 February 2014
Available online 19 February 2014

KEYWORDS
Cost-effectiveness;
Added value;
Seizure;
Neuroimaging;
Temporal lobe epilepsy;
Epilepsy

Summary The costs, benefits and risks associated with diagnostic imaging investigations for epilepsy surgery necessitate the identification of an optimal pathway in the pre-surgical workup. In order to assess the added value of additional investigations a full cost-effectiveness evaluation should be conducted, taking into account all of the life-time costs and benefits associated with undertaking additional investigations. This paper considers and applies the appropriate framework against which a full evaluation should be assessed.

We conducted a systematic review to evaluate the progression of the literature through this framework, finding that only isolated elements of added value have been appropriately evaluated. The results from applying the full added value framework are also presented, identifying an optimal strategy for pre-surgical evaluation for temporal lobe epilepsy surgery. Our results suggest that additional FDG—PET and invasive EEG investigations after an initially discordant MRI and video-EEG appears cost-effective, and that the value of subsequent invasive-EEGs is closely linked to the maintenance of longer-term benefits after surgery.

It is integral to the evaluation of imaging technologies in the work-up for epilepsy surgery that the impact of the use of these technologies on clinical decision-making, and on further treatment decisions, is considered fully when informing cost-effectiveness.

Introduction

Medical imaging represents one of the fastest growing areas of medical expenditure (Neiman Institute, 2012), this growth has been driven by both an increase in the supply of non-invasive techniques including Computed Tomography

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http://dx.doi.org/10.1016/j.eplepsyres.2014.02.002
0920-1211/

(CT), Positron Emission Tomography (PET), Single-Photon Emission Computed Tomography (SPECT) and Magnetic Resonance Imaging (MRI) technologies as well as greatly increased demand by health care providers (Iglehart, 2006). In any area of significant spend it is important to ensure that growth is based on both clinical evidence as well as value for money. Consideration of value for money ensures that additional expenditure results in the greatest potential gain in health.

However, to date there has been little research conducted, in epilepsy or more generally, that has sufficiently considered the value for money of imaging strategies available through cost-effectiveness methods. (Schaafsma et al., 2009; Burch et al., 2012a) The limited maturity of the existing research may partly be explained by the difficulty in assessing the value of an additional medical imaging technology, and lack of an accepted standard of analysis. The difficulty in assessing added value in this context is largely a result of the difficult interpretation of a test results (Hogstrom and Sverre, 1996), difficulty in interpreting and assessing diagnostic accuracy (Burch et al., 2012b), and the linking of these results to the long term clinical outcomes (Schaafsma et al., 2009; Trikalinos et al., 2009).

To date there has been little consideration of the appropriate methods with which to consider the added economic value of imaging technologies in general, with the majority focussing solely on the clinical value alone. Authors such as Schaafsma et al. (2009) and Fryback and Thornbury (1991) have presented hierarchies of evidence required to consider the added value of a diagnostic technology. A common feature of these hierarchies is that the lower end considers assessments of diagnostic performance with the higher stages considering change in clinical outcome and cost-effectiveness. In general, the evaluation of diagnostics is typically limited to the lower end of the hierarchy (Trikalinos et al., 2009). The frameworks highlight that the added value of a diagnostic technology depends not only on diagnostic accuracy but also how the results impact on subsequent treatment decisions, as well as the associated final clinical outcomes. We will consider the application of the Schaafsma hierarchy, shown in Box 1, to the example of pre-surgical workup for temporal lobe epilepsy surgery.

Surgical intervention to resect the epileptic focus has the potential to significantly improve patient outcomes (NICE, 2012). Medical imaging technologies are increasingly used to try to identify structural or functional changes to help localise the likely site of the seizure focus and inform decisions about further investigation and whether and how to proceed with surgery. Due to the costs and potential adverse events associated with these medical imaging techniques the optimal selection and order of the imaging tests is important. A systematic review of the literature found that no research had sufficiently considered the added value of imaging technologies in the pre-surgical workup of epilepsy patients, using cost-effectiveness methods (Burch et al., 2012a).

An additional review was conducted to evaluate previous research into the clinical value of tests (stage 2 of the Schaafsma hierarchy) in this area (Burch et al., 2012a) The review found a single study, by Uijl et al. (2007), which assessed the impact of additional investigations (FDG—PET and subsequent invasive-EEG) on the decision to proceed to surgery after discordant video-EEG and MRI findings. The study considered the short-term outcome following surgery (stages 1, 2 and 3); costs and longer-term outcomes were not considered.

Box 1 The Schaafsma framework

1. The first step of evaluation is to identify the *test characteristics* of the imaging technology. These are the parameters that define the clinical ability of the technology, for example the diagnostic accuracy, and the sensitivity and specificity.
2. The second considers the *clinical value* of a test. As the tests involved in pre-treatment workup are usually used in sequence the additional information provided by the test to the decision maker must be considered, rather than the test's ability in isolation.
3. Thirdly the resultant *clinical outcome* is important to the evaluation of the technology being considered. As the justification for additional imaging tests is not the direct output of the test but the potential access to beneficial medical treatments, such as surgery, it is vital to consider the potential clinical outcomes of the range of different treatment options available once the test result is defined.
4. Finally is the role of *cost-effectiveness*. Schaafsma argues that the only suitable method to combine all of the information collected in the previous stages is the use of a full cost-effectiveness evaluation.

This paper uses the study by Uijl et al. in a worked example to present a framework for assessing the full added value of additional imaging tests in the case of pre-surgical workup for temporal lobe epilepsy surgery, using the Schaafsma framework (Box 1). The framework will be used to evaluate the cost-effectiveness of the range of clinical strategies presented by Uijl et al., the uncertainty in these results will be explored through the use of a scenario analysis as well as probabilistic sensitivity analysis (PSA).

Methods

A decision model was constructed to allow an evaluation of added value in the pre-surgical workup of patient with epilepsy consistent with the Schaafsma framework (Box 1). A decision model is a quantitative approach used to combine evidence from a variety of sources to inform the evaluation of added value. It does so through the consideration of the diagnostics outcomes of the tests alongside the longer term implications of the range of decision strategies. This approach facilitates an assessment of the relative value of each strategy available to the decision maker, in terms of costs and health related quality of life of the patient, and ultimately allows the optimal strategy to be identified through a consideration of the cost-effectiveness of each strategy. Uncertainty in the model inputs can be propagated to allow for a consideration of the likelihood and implications of an incorrect decision being made by the decision maker (Drummond et al., 2005).