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Title **The Clinical Effectiveness and Cost Effectiveness of Newer Drugs for Children with Epilepsy. A Systematic Review**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

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Aim

To examine the clinical and cost effectiveness of newer antiepileptic drugs (AEDs) for epilepsy in children: gabapentin, lamotrigine, levetiracetam, oxcarbazepine, tiagabine, topiramate, and vigabatrin.

Conclusions and results

The quality of the randomized controlled trial (RCT) data was generally poor. For each of the epilepsy subtypes considered in RCTs identified for this review (partial epilepsy with or without secondary generalization, Lennox-Gastaut syndrome, infantile spasms, absence epilepsy, and benign epilepsy with centrotemporal spikes), placebo-controlled trials provide some evidence that the newer agents tested are of some value in treating these conditions. Where active controls have been used, the limited evidence available does not indicate a difference in effectiveness between newer and older drugs. The data are not sufficient to inform a prescribing strategy for any of the newer agents in any of these conditions. No clinical evidence suggests that the newer agents should be considered as first-choice treatment in any form of epilepsy in children. Annual drug costs of the newer agents range from around 400 to 1200 British pounds (GBP), depending on age and concomitant medications. An AED that is ineffective or has intolerable side effects will only be used for a short period, and many patients achieving seizure freedom will successfully withdraw from drug treatment without relapsing. The results of the decision-analytic model do not suggest that the use of the newer agents in any of the scenarios considered is clearly cost effective but, similarly, do not indicate that they are clearly not cost effective.

Recommendations

The prognosis for children diagnosed with epilepsy is generally good, with a large proportion responding well to the first treatment. However, for those not responding well to treatment the clinical goal is to find an optimal balance between the benefits and side effects of treatment. For the newly, or recently, diagnosed population, the key question for the newer drugs is how soon they should be tried. The cost effectiveness of using these agents early, in place of older agents, will depend on the effectiveness and tolerability of these agents compared with the older agents. Evidence from the available trial data suggests that the newer agents are no more effective, but may be somewhat better tolerated than the older agents. Hence, the cost effectiveness for early use will depend on the trade off between effectiveness and tolerability, both in terms of overall (long-term) treatment retention and overall utility associated with effects on seizure rate and side effects. The date are insufficient available to estimate accurately the nature of this trade-off, either in terms of long-term treatment retention or utility. Better information is required from RCTs before any rational evidence-based prescribing strategy could be developed.

Methods

Studies were assessed for inclusion according to predefined criteria. Data extraction and quality assessment were also undertaken. A decision-analytic model was constructed to estimate the cost effectiveness of the newer agents in children with partial seizures, the only condition where there were sufficient trial data to inform a model.

Further research/reviews required

Diagnosis-specific decision-analytic models are required. Further research may be required to inform parameter values adequately with respect to epidemiology and clinical practice.

Written by Dr Josie Sandercock, Public Health & Epidemiology, University of Birmingham, United Kingdom

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