Platform Session

Monday July 3, 2006
12:00–13:30
Hall I

Platform Session
Drug Therapy I

001 A RANDOMISED OPEN-LABEL COMPARISON OF THE EF-FICACY, TOLERABILITY, AND HORMONAL EFFECTS OF SODIUM VALPROATE AND LAMOTRIGINE MONOTHERAPY IN NEWLY-DIAGNOSED EPILEPSY

G. Sills, L. Stephen, E. Butler, P. Parker, K. Kelly, E. Wilson, and M. Brodie (Epilepsy Unit, University Division of Cardiovascular & Medical Sciences, Western Infirmary, Glasgow, Scotland)

Purpose: This study was designed to compare monotherapy with sodium valproate (VPA) and lamotrigine (LTG) in patients with newly diagnosed epilepsy.

Method: A total of 226 untreated patients (116 male) with a recent diagnosis of epilepsy (60 idiopathic generalised epilepsy, 149 localisation-related epilepsy, 17 unclassified) were randomised to receive either VPA or LTG as monotherapy. Median age was 35 years (range 13–80 years). Patients were followed-up at six-weekly intervals and remained in the study until reaching a predetermined end point (12 month seizure-freedom; intolerable side-effects including idiosyncratic reaction; lack of efficacy despite adequate dosing).

Results: Twenty-nine patients were excluded from the analysis (24 lost to follow-up, 3 withdrawn consent, 1 protocol violator, 1 non-epileptic attack). A total of 197 patients reached an end point, with 126 (63%) becoming seizure-free for a minimum period of 12 months on initial monotherapy. Of these, 64 took VPA (67% of VPA completers; median dose = 1000 mg, range 600–3000 mg) and 62 took LTG (60% of LTG completers; median dose = 200 mg, range 100–700 mg). Thirty-eight patients (24 VPA, 14 LTG) experienced intolerable side effects, while a further 33 (18 VPA, 15 LTG) failed to report acceptable efficacy despite adequate dosing. There were no significant changes in mean (±SEM) serum concentrations of testosterone (p = 0.225), SHBG (p = 0.201), or androstenedione (p = 0.394) in either patient group at 6 months after initiation of therapy.

Conclusion: These findings suggest that there is little (if any) difference in the efficacy, tolerability, or hormonal effects of VPA or LTG monotherapy in the treatment of newly diagnosed epilepsy.

002 MULTICENTRE RANDOMISED CONTROLLED TRIAL COMPARING STANDARD AND NEW ANTI-EPILEPTIC DRUGS (SANAD)

1A. Marson, 1C. Tudur Smith, 1P. Williamson, 2D. Smith, 1A. Jacoby, and 1D. Chadwick (1University of Liverpool, Liverpool, UK, 2The Walton Centre, Liverpool, UK)

Purpose: There is a paucity of randomised controlled trials (RCTs) that inform a choice among antiepileptic drugs, and existing trials have largely failed to examine longer term effectiveness. SANAD assesses these longer term outcomes.

Method: SANAD is a multicentre, UK based, unblinded RCT recruiting patients over the age of 5 years, requiring antiepileptic drug monotherapy. SANAD has 2 arms. Patients for whom carbamazepine was the standard drug (arm A) were randomised to carbamazepine, gabapentin, lamotrigine, oxcarbazepine or topiramate. Patients for whom valproate was the standard drug (arm B) were randomised to valproate, lamotrigine or topiramate. Recruitment commenced in 1999, ended 2005, and follow up ended in 2005. Outcomes included time to the following events: withdrawal of allocated treatment, 12 month remission from seizures, first seizure, as well as adverse events, quality of life and cost effectiveness.

Results: 2443 patients were recruited, for whom we have 7799 patient years follow up, 95% of the maximum possible. 1721 patients entered arm A, 378 were allocated carbamazepine, 377 gabapentin, 378 lamotrigine, 210 oxcarbazepine and 378 topiramate. The mean age was 38.3 yrs, 55% were male and 89% were classified as having a partial epilepsy syndrome. 716 patients entered arm B, 238 were allocated valproate, 259 lamotrigine and 239 topiramate. The mean age was 25.5 yrs, 60% were male, and 62% were classified as having an idiopathic generalised epilepsy syndrome. Full clinical results will be presented.

Conclusion: Large multicentre studies examining the longer term effects of antiepileptic drugs, such as SANAD, are required to inform clinical practice.

003 AN INTERNATIONAL MULTICENTER DOUBLE-BLIND DOUBLE-DUMMY RANDOMISED TRIAL COMPARING LAMOTRIGINE AND SLOW-RELEASE CARBAMAZEPINE FOR TREATING NEWLY DIAGNOSED EPILEPSY IN THE ELDERLY

1E. Saetre, 2E. Perucca, 3J. Isojärvi, and 4L. Gjerstad (1Ullevaal University Hospital, Oslo, Norway 2University of Pavia, Pavia, Italy, 3University of Oulu, Oulu, Finland / Jazz Pharmaceuticals, Palo Alto, Ca, USA, 4University of Oslo, Oslo, Norway)

Purpose: To compare lamotrigine (LTG) and slow-release carbamazepine (CBZ) in the treatment of newly diagnosed epilepsy in the elderly.

Method: Patients aged >65 years with a history of two or more unprovoked partial and/or tonic–clonic seizures received LTG (n = 93) or CBZ (n = 91) in a randomised double-blind 40-week trial. Target dose was 100 mg/day for LTG and 400 mg/day for CBZ; dose escalation was 4 weeks and dose adjustments according to response were permitted.

Results: In the LTG group, 68 patients (73%) completed the trial compared with 61 (67%) in the CBZ group (not significant). Time to withdrawal from any cause did not differ between groups (p = 0.34). The number of subjects who completed the study and were seizure-free during weeks 4–40 was 37 (40%) in the LTG group and 46 (50%) in the CBZ group. Adverse events leading to withdrawal occurred in 26 (28%) CBZ-treated subjects and 15 LTG-treated subjects (16%). The Liverpool Adverse Event Profile (AEP) score showed a non-significant advantage for LTG.

Conclusion: LTG and CBZ showed comparable effectiveness, with a trend for higher seizure-free rates for CBZ and better tolerability for LTG. Acknowledgment: Supported by GlaxoSmithKline.

004 EFFICACY OF LEVETIRACETAM MONOTHERAPY: RANDOMISED DOUBLE-BLIND HEAD-TO-HEAD COMPARISON WITH CARBAMAZEPINE-CR IN NEWLY DIAGNOSED EPILEPSY PATIENTS WITH PARTIAL ONSET OR GENERALISED TONIC–CLONIC SEIZURES

1M. Brodie, 1E. Ben-Menachem, 1E. Perucca, and N1061 Study Group (1Epilepsy Unit, Western Infirmary, Glasgow, UK, 2Department of Clinical Neuroscience, Sahlgrenska University Hospital, Göteborg, Sweden, 3Clinical Pharmacology Unit, University of Pavia, Italy)
views on services and their opinions about how access for men could be improved. 

Method: 1200 questionnaires were distributed to a random sample of men who had contacted Epilepsy Action helpline in the previous year; 373 were returned and analysed.

Results: 27% were seizure free at time of study, 48% had “occasional” seizures, 93% took AEDs, 39% were in employment, 46% lived with a partner and 33% said epilepsy had affected their relationship with their partner, and 77% their quality of life. The most commonly reported impact on lifestyle was driving at 69%, 74% considered themselves, “knowledgeable” or “very knowledgeable” about their epilepsy, 43% said they would turn first to their GP for advice, 16%, their consultant, 11.8% a specialist nurse. When asked what they would do if they had a specific question about epilepsy 85% said they would find out for themselves. When asked to give their 3 preferred options for accessing information 57% said their GP, 45% consultant, 34% the internet and 33% a telephone helpline. Specialist nurses were ranked 5 in their order of preference after books and leaflets.

Conclusion: Men may differ from women in how they access information about their condition. Further studies are needed to gain a greater insight into the needs of men with epilepsy.

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A COMPARISON OF SELF-REPORTED QUALITY OF LIFE BETWEEN PATIENTS WITH EPILEPSY AND NEUROCARDIOGENIC SYNCOPE

H. Fowler, J. Santhouse, C. Carrier, S. Arya, and S. Duncan

1Department of Behavioural Medicine Greater Manchester Neurosciences Centre Hope Hospital, Salford, UK, 2Department of Neurology Greater Manchester Neurosciences Centre Hope Hospital, Salford, UK, 3Department of Cardiology Royal Albert Edward Infirmary, Wigan Lancashire, UK

Purpose: Generalised tonic-clonic seizures and complex partial seizures have very different pathophysiological mechanisms to syncope, but share a final common pathway of loss of consciousness with social disruption. Quality of life has been studied in epilepsy and to a lesser extent syncope; there have been no studies comparing these two populations.

Method: Fifty-two consecutive patients between the ages of 16 and 60 referred for tilt table testing were recruited. Patients had at least 2 episodes of syncope in the preceding year. Ninety-two consecutive patients attending an epilepsy clinic (71 localisation related and 21 IGE) were recruited. Twenty-eight had been seizure free for at least one year at time of study. A control group of 100 people consisting of spouses/partners of patients and hospital employees were recruited. All completed HADS and WHO-QOL-Bref.

Results: There were no significant differences between the syncope and seizure groups in depression and anxiety subscales of the HADS. Both syncope and seizure groups were significantly more depressed and anxious than controls (p < 0.01). There were no significant differences between the seizure and syncope groups in overall quality of life and in the 4 domains of the WHO-QOL-Bref. In 3 of the 4 domains of WHO-QOL-Bref the epilepsy and syncope groups, however, reported significantly poorer quality of life than controls (p < 0.001).

Conclusion: This is to our knowledge the only study comparing quality of life in syncope and epilepsy. If our results are replicated it implies repeated loss of consciousness has as great an impact on quality of life as epilepsy’s many comorbidities.

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DESIGN AND DEVELOPMENT OF A WEB-BASED DATABASE SYSTEM FOR THE MANAGEMENT AND ANALYSIS OF EPILEPSY PATIENTS’ DATA: EPILEPSY DATABASE EPILDA


1Biomedical Simulations and Imaging Laboratory, National Technical University of Athens, 2Epilepsy Surgical Treatment Unit, Department of Neurosurgery, University of Athens, “Evangelismos” Hospital, 3Greek Center for Neurosurgical Research “Prof. Petros Kokkalis”

Purpose: To present a database system (EPILDA), designed and developed for the efficient management, processing and analysis of epidemiological, clinical and other patient related data concerning epilepsy in Greece. Furthermore, given the high diversity of cases and the variety of available treatment approaches, the system aims at assisting objective therapy evaluation.

Method: The EPILDA system is based on web technologies enabling accessibility from remote medical centres and hospitals. The study and processing of epilepsy data is accomplished via a user friendly interface on either desktop PCs or portable devices such as laptops or PDAs. Since medical data protection is of paramount importance, the implementation of strict security measures at the data storage and transmission level as well as at the application level is the cornerstone of the EPILDA system.

Results: The EPILDA system maintains data related to the general characteristics of a patient, the patient’s visits, the drug treatment, the characteristics of epilepsy, medical imaging data, surgical treatment data, EEG and video-EEG recordings. The basic system functionalities comprise data entry, search and review as well as the generation of reports based on specific criteria.

Conclusion: The proposed system can (a) assist the user toward the efficient management of a large volume of available epilepsy-related data (b) contribute to the automation of statistical analysis and towards the extraction of major epidemiological conclusions, as well as towards therapy planning, monitoring, and evaluation.

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DIABETES MELLITUS AND EPILEPTIC SEIZURES

H. Bozdemir, K. Aslan, and Y. Sarýca (Neurology, Istanbul, Turkey)

Purpose: Disturbance of glucose regulation in patients with diabetes may result in an epileptic disorder.

Method: Twenty-six patients (12 women, 14 men) with a mean age of 54 years were selected for this study.

Results: For 7 patients mean epilepsy duration was 12 years and mean diabetes mellitus (DM) was 4.5 years (Group A). For 19 patients the mean DM duration was 11 years and epileptic disorder was detected on an average of 4 years after DM diagnosis (Group B). Epileptic disorder was primary generalised in 3, and partially generalised in 23 patients. For Group B stroke (n = 7), DM (n = 11), MTS (n = 1) were risk factors for epilepsy. The aetiologic factors of group A were, tumour, head trauma, idiopathic (3) and cryptogenic (1). EEG revealed active subkortical epileptic abnormalities in 2, lateralized abnormal activity in 14. MRI revealed cortical infarct in 1 of the group A, and in 4 of the group B patients. In 15 of the patients in group B antiepileptic treatment (AET) was proposed. For the remaining patients, for 2 convulsions began during a hypoglicemic coma, and in 2 during a nonketotic hyperglycemic coma (NKHC) state. For these patients convulsions were under control after blood glucose regulation. AET was proposed to the patients who were hospitalised because of NKHC and right hemiparesis.

Conclusion: Cerebral ischemia or infarct can be detected without hypo or hyperglycemic coma, and these cerebral changes can be risk factors for an epileptic disorder.

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UNVERRICHT-LUNDBOURG DISEASE: A CONDITION WITH SELF-LIMITED PROGRESSION

E. Ferlazzo, A. Magauda, V. Nguyen, and P. Genton (Centre for Diagnosis and Care of Epilepsy, Department of Neurosciences, Anaesthesiological and Psychiatric Sciences, University of Messina, Italy, Centre Saint Paul, Marseille, France)

Purpose: To assess the long-term evolution of Unverricht-Lundborg disease (ULD), especially concerning myoclonus, seizures and EEG characteristics.