EMPIRICAL EVIDENCE. The objective of this study was to evaluate whether there were differences in adverse event reporting for propoxyphene by age group using a large post-marketing safety surveillance database. METHODS: Analysis was conducted using the 2005–2008 Adverse Event Reporting System (AERS) data in the US, which was developed to support the FDA’s post-marketing safety surveillance program for approved products. Adverse event reports with propoxyphene as primary, secondary, or interacting drug were categorized into central nervous system (CNS) and gastrointestinal (GI) adverse events (AEs). Logistic regressions were used to assess the risk of CNS and GI adverse events (AEs) among the elderly (age ≥ 65) and younger patients (age < 65) controlling for gender and those reporting the AEs. Proportional reporting ratios (PRR) for the propoxyphene-AE combination were also computed for the elderly and younger patients. RESULTS: In the period 2005–2008, a total of 2497 propoxyphene-AE combinations were reported, 261 were CNS related and 127 were GI related. In multivariate analysis, controlling for gender and those reporting the AEs, no significant differences were observed in the risk of CNS-related AEs (Odds ratio 0.827; 95% CI: 0.619–1.105; p = 0.199) or GI-related AEs (Odds ratio 1.216; 95% CI: 0.832–1.778; p = 0.313) among elderly versus young patients. Among the elderly, the PRR for propoxyphene-CNS AEs was 0.795 and the PRR for propoxyphene-GI AEs was 0.596. These were similar to the PRRs among younger patients, which were 0.700 and 0.439, respectively. CONCLUSIONS: Using a voluntary post-marketing surveillance database, the study found no differences in the extent of CNS AEs and GI AEs reported with propoxyphene among elderly patients versus younger patients.
risk group definitions lead to heterogeneity in CR rates. Only a small number of studies will provide valid estimates of the CR rates in patients with primary AML aged 16–60 years. However, this restriction may reduce the reliability of the estimates, because the estimates will be based on fewer patients. This will thereby increase the uncertainty around the ICER of new methods.

A RETROSPECTIVE CHART REVIEW OF THE TREATMENT OF PHENYLKETONURIA IN THE UK AND ASSOCIATED CLINICAL AND HEALTH OUTCOMES

PATIENTS AND METHODS

We conducted a retrospective chart review of the treatment of PKU patients aged ≥18 years who were in contact with three patient service organizations in the UK. The organizations were the National Society for Phenylketonuria (NSPKU), the Phenylketonuria Support Group (PKS), and the Phenylketonuria Education and Information Service (PEIS). The study was approved by the local ethics committee and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent.

RESULTS

A total of 316 patients (238 males, 78 females) were included in the study. The mean age of the patients at the time of diagnosis was 0.96 years (range, 0–59 years). The mean age at the time of the chart review was 26.2 years (range, 0–84 years). The mean age of the patients at the time of the chart review was 26.2 years (range, 0–84 years).

CONCLUSIONS

The majority of PKU patients within this study had well-controlled Phe levels, however a number may benefit from additional treatment.

EFFECT OF MODERATE-INTENSITY EXERCISE TRAINING AND DIET ON BODY COMPOSITION AND EXERCISE CAPACITY IN OBESITE CHILDREN

TOHT–STEINHAUS V1, GOMBOC K1, LENCI Z2, STAHL P2, FARENZ A3, BOGÁT FÁZER Z2, BALE E1, CÁSZÁRNÉ GOMBOS G1, KRISSZBACHER I3, SCHMIDT B1

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OBJECTIVES: Childhood obesity is a serious health problem favouring the early development of insulin resistance, type 2 diabetes mellitus and cardiovascular diseases. Our main goal was to investigate multidisciplinary weight control program in exercising training, maximal fat oxidation (FATmax) zone and diet in three different age groups on body composition and physical fitness of overweight children. METHODS: Thirty overweight pupils (BMI > percentile 90%) of three different elementary schools (age: 11.8 ± 2.0 years) were included. Body composition was determined by bioelectric impedance method. Gradual increase test (Jager Oxygen Monit.400) was used to determine whole body peak fat oxidation by indirect calorimeter. Training heart rate interval was determined by as ± 10% of FATmax. Physical exercises were prescribed by the physiotherapist. Exercise training was performed 2 times/week in the school using heart rate monitor under the control of the games master. The training periods were 56, 101 and 146 days. Dietary proposal was given for the parents of the children. RESULTS: At the end of the weight-control program percentage of fat mass decreased (35.7% ± 4.6 vs. 33.0% ± 5.3%; p < 0.001), muscle mass increased (22.8% ± 4.6 vs. 24.4% ± 5.2 kg; p < 0.001). VO2max increased at the longest training period only (1841 ± 620 vs. 2011 ± 642 ml · min⁻¹; p = 0.043). CONCLUSIONS: Moderate intensity exercise training and diet resulted in favourable changes in the body composition in a short term whereas the significant improvement of VO2max was observed after 9 months of the training. FOCUS: Expected effects on improved data completeness and quality in FOs have been successful, optimizing the value of the database. Regular, accurate data collection and audit will increase the quality of FOs and lead to an improved understanding of the management of Fabry disease.

TAPENTADOL EXTENDED RELEASE (ER) FOR CHRONIC LOW BACK PAIN-RESULTS OF EUROQOL-5 DIMENSION (EQ-SD) AND SHORT FORM-36 (SF-36) HEALTH STATUS QUESTIONNAIRES

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OBJECTIVES: To evaluate the efficacy and safety of tapentadol ER in patients with moderate-to-severe chronic low back pain. Health status was evaluated using SF-36 and EQ-SD questionnaires. METHODS: Patients received controlled, adjusted individually doses of tapentadol ER (100–250 mg) Quarterly and monthly. RESULTS: EQ-SD evaluates mobility, self-care, usual activities, pain/discomfort, and anxiety/depression; SF-36 evaluates physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health dimensions. RESULTS: Of 981 patients randomized, 958 were evaluated for efficacy. Compared with placebo, improvements from baseline to endpoint in the SF-36 physical component summary score were significantly greater with tapentadol ER (1.9 ± 0.8). Pre-index period were excluded. Two study cohorts were constructed based on adherence to treatment at maximal fat oxidation (FATmax) zone and diet in three different duration of the each episode: 0.285). Compared with placebo, treatment at maximal FATmax zone and diet was associated with: 1) a core dataset was developed to enhance the robustness of data capture: 1) a core dataset was developed for assessing disease progression and therapy response, 2) focus was directed at those participating centers with ≥200 patients enrolled in FOs, and 3) research associates were employed to monitor data capture and quality. Random samples (25%) of all enrolled patients were selected from the years 2004 and 2007, before and after the changes, respectively. The completeness of data capture was determined for 10 core variables in each year. RESULTS: Data capture was analyzed for 197 of the 815 patients enrolled in FOs in 2004 and for 404 of the 1616 patients enrolled in 2007. Increase in data capture occurred from 9 of the 10 core variables: 30.3% in 2004 and 32.1% in 2007. Changes in completeness of data capture were mainly due to improved data definitions and completeness. CONCLUSIONS: The completeness of data capture was determined for 10 core variables in each year. Data capture was analyzed for 197 of the 815 patients enrolled in FOs in 2004 and for 404 of the 1616 patients enrolled in 2007. Increase in data capture occurred from 9 of the 10 core variables: 30.3% in 2004 and 32.1% in 2007. Changes in completeness of data capture were mainly due to improved data definitions and completeness. CONCLUSIONS: The completeness of data capture was determined for 10 core variables in each year. Data capture was analyzed for 197 of the 815 patients enrolled in FOs in 2004 and for 404 of the 1616 patients enrolled in 2007. Increase in data capture occurred from 9 of the 10 core variables: 30.3% in 2004 and 32.1% in 2007. Changes in completeness of data capture were mainly due to improved data definitions and completeness. CONCLUSIONS: The completeness of data capture was determined for 10 core variables in each year.