COST-EFFECTIVENESS OF QT EPINE, ARIPIPRAZOLE OR OLANZAPINE IN PATIENTS WITH BIPOLAR DEPRESSION IN THE RUSSIAN FEDERATION

Kulikov A, Komarov I

OBJECTIVES: To assess the efficiency of the atypical antipsychotics used to reduce relapses in bipolar disorder, taking into account costs and effectiveness (measured as QALY). METHODS: A cost-effectiveness analysis (CEA) was conducted. The Russian health care system perspective and a 5 year temporal horizon have been used. An annual discount rate was assumed to be 5%. Taking into account the last literature review on bipolar disorder, four fundamental aspects related with bipolar disorder management were analyzed: preventive relapse rates, inpatient treatment, outpatient treatment and hospitalization rates. The health care direct costs corresponding to the drug acquisition costs have been adjusted to 2012 USD using consumer price index. The expected outcome was adjusted to 2012 USD using consumer price index. For reference, accepted exchange rate was 1 EUR = 40 RUB. RESULTS: Taking into account rates of prevented relapse following cost-effectiveness ratios (CER) were obtained: 156,915 RUB (3,923 EUR) in quetiapine group, 429,362 RUB (10,734 EUR) in aripiprazole group and 221,879 RUB (5,547 EUR) in olanzapine group. Using QALY values CER were calculated for: 185,236 RUB (4,631 EUR) in quetiapine group, 478,433 RUB (11,961 EUR) in aripiprazole group and 254,100 RUB (6,353 EUR) in olanzapine group. CONCLUSIONS: Quetiapine in the treatment of BPD depression episodes is a dominant compared with aripiprazole or olanzapine.

COST-EFFECTIVENESS OF ATYPICAL ANTIPSYCHOTICS FOR THE TREATMENT OF RELAPSE PREVENTION FOR BIPOLAR DISORDER: THE RUSSIAN PERSPECTIVE

Kulikov A, Komarov I

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COST-UTILITY OF TWO SHORT-TERM PSYCHOTHERAPIES IN THE TREATMENT OF DEPRESSIVE AND ANXIETY DISORDERS DURING A THREE-YEAR FOLLOW-UP

Malanine T, Härkänen T, Virtala E, Lindfors O, Tillman P, Knekt P

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OBJECTIVES: Different types of psychotherapy, alone or together with pharmaceuticals, are used extensively in the treatment of depressive and anxiety disorders. However, only a few studies thus far have addressed the cost-effectiveness of these treatments. The aim of this study is to compare the direct health care costs and the quality of life of persons who have suffered from depression or anxiety and have been treated either with short-term psychodynamic psychotherapy (SP), behavioral therapy (BTB) or solution-focused therapy (SFT). The follow-up period was three years. METHODS: A total of 198 outpatients aged 20–45 years suffering from mood or anxiety disorder were randomized to SP or BTB. Patients’ quality of life was assessed using Chulbons Life Situation Survey (LSS). The assessments took place at baseline and at 7, 12 and 36 months after the start of the therapy. All direct costs due to mental health problems incurred during the three-year follow-up period were taken into account in the analysis. RESULTS: During the first 7 months patients’ quality of life improved considerably, with mean LSS scores increasing from about 70 to about 93 in both groups. This change was also statistically significant. After the 7th month some minor improvements continued to be observed in quality of life. At the end of the follow-up period the mean LSS scores were in both groups somewhat below 100, a threshold for very good life quality. The differences between the two groups were very small at every measurement point and not statistically significant. The direct costs were about equal in both groups. The small positive changes observed in the quality of life after the 7th month were at least partly due to auxiliary treatments whose costs were much higher than the costs of SP or SFT. CONCLUSIONS: There is little appreciable difference in cost-utility between SP and SFT.

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**PMH44**

**THE SITUATION OF THE FAMILIES WITH AUTISTIC CHILDREN IN HUNGARY**

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**OBJECTIVES:** To examine the circumstances of the recognition of the autism, the problems in connection with the child as well as the opportunities, deficiencies of the support. **METHODS:** During the research as the first step an open-ended interview was conducted which, was recorded and transcribed. As the second step the families were reached through them. A total of 358 postal examination questionnaires were sent; the interviewers visited 312 families. During my analysis the data of the samples between year 0-18 were used (276 interviews, during which, one item was removed and four others were modified). **RESULTS:** The first symptoms of autism are perceived foremost by the parents that is followed by an at least 2 years period till the diagnosis. Only 30% of the children speak well, 27% are able to make basic care. The parents always understand them. The 38% of children have slight or severe insomnia. A total of 84% of the children have frequent or permanent behavioural disorders. Due to the child’s autism the families are isolated, 40% of the parents have been unemployed since the birth of their child. The assistance or communication between the concerned families is incidental (5%). The 36% of the parents experienced discrimination in the field of health care. The care of people with disabilities lacks from the health visitors’ graduate training. Early recognition and the diagnose. Our other goal is to build a comprehensive training system to broaden the knowledge of the health professionals.

**PMH45**

**CONSEQUENCES OF THE REDUCTION OF ALCOHOL CONSUMPTION ON PATIENT’S REPORTED OUTCOMES WITH THE USE OF NALMEFENE**

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**OBJECTIVES:** To evaluate the impact on alcohol-dependent patients’ reported outcomes of the as-needed use of nalmefene versus placebo in the treatment of alcohol consumption. **METHODS:** Two 6-month randomized, double-blind, placebo-controlled, efficacy studies were conducted in Europe (ESENSE 1 [NCT00811720]; ESENSE 2 [NCT00814261]). All patients took part in a minimum of 6 months intervention (BREENDA) to support behavioural change and adherence to treatment. The Short Form Health Survey (SF-36), the EuroQol-5 Dimensions (EQ-5D) and the Drinker Inventory of Consequences (DrInC-2R) questionnaires were administered at baseline, weeks 12 and 24. Post-hoc analyses of the pooled subgroups of patients with a high drinking risk level (men:>60 g/day; women:>40 g/day) were performed. **RESULTS:** The S-MDD is a 35-item PRO measure intended for use as an end point in MDD clinical trials to support medical product labeling. It was developed and reviewed by the FDA PRO Qualification Panel. Qualitative interviews have provided evidence for content validity. Future quantitative studies will confirm the S-MDD’s measurement properties and support FDA qualification.

**PMH46**

**ESTIMATING THE ASSOCIATION BETWEEN QT PROLONGATION AND SSRI UTILIZATION FROM THE FDA’S ADVERSE EVENT REPORTS**

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**OBJECTIVES:** To analyze the association between QT prolongation and TdP and adverse event and the utilization of citalopram and other SSRIs. **METHODS:** Retrospective, descriptive study used the U.S. FDA Adverse Event Reporting System (FAERS) database. The database included 7,840,225 adverse events associated with SSRI drugs from 1997 fourth quarter to 2011 third quarter. The number of reported QT-prolongation and TdP cases associated with each study drug was calculated over time. Furthermore, for each case, dosage of the drug, withdrawal or discontinuation in the report, was recorded. **RESULTS:** A total of 5,088 reports were associated with QT prolongation and TdP were associated with SSRI drugs over the 14-year study period. Only 18% (219) of the adverse event reports were related specifically to citalopram, while the rest were related to other SSRI drugs. There were 1,102 reports for women and 727 for men and 202 wereander gender information. The rate of QT prolongation and TdP associated with dosages of 20 mg, 40 mg, and 60 mg of citalopram per day were 39%, 21%, and 2%, respectively. **CONCLUSIONS:** Citalopram is still in use without dosage withdrawal. So we were unable to draw any conclusions regarding dosage-related events. **RESULTS:** The conclusions confirmed an association between the use of citalopram with QT prolongation and TdP. Furthermore, the association was not limited to citalopram alone but was widespread across the SSRIs. There were more adverse events observed for women than for men. The gender dependency was not established in this study. Future studies are warranted.

**PMH47**

**USING TRANSLATABILITY ASSESSMENT TO REFINE A PATIENT- REPORTED OUTCOME (PRO) MEASURE DURING THE DEVELOPMENT PROCESS**

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**OBJECTIVES:** To complete qualitative concept elicitation (CE) and cognitive interviews leading to preliminary development of a patient-reported outcome (PRO) measure to assess treatment benefit in major depressive disorder (MDD) clinical trials. **METHODS:** Qualitative interviews were conducted with adult MDD patients in the US who recently experienced a major depressive event. All participants had a Hamilt on Depression Rating Scale (HDRS) total score >18 at screening. Experienced interviewers conducted CE and cognitive interview sessions using semi-structured interview guides. The CE interview guide was used to create spontaneous and relevant narratives. A total of 191 reported outcome (PRO) measures were coded for qualitative content analysis using Atlas.ti, and the cognitive interview transcripts were summarized in cognitive report tables. **RESULTS:** Forty patients (mean age: 46.2; 67.5% female; 45.0% white (non-Hispanic) participated in the CE interviews. Mean (SD) HDRS total score of the participants was 24.4 (4.3). A total of 3,022 symptom codes, representing 91 different concepts were derived from the transcripts. Data from the CE interviews was considered alongside existing literature and clinical expert opinion during an item-generation meeting, leading to development of a 36-item measure with a 5-point response scale. Subsequently, fifteen patients participated in three waves of cognitive interviews in accordance with an item bank (PMH47) derived from CE data. **CONCLUSIONS:** This retrospective, descriptive study used the U.S. FDA Adverse Event Reporting System (FAERS) database. The database included 7,840,225 adverse events associated with SSRI drugs from 1997 fourth quarter to 2011 third quarter. The number of reported QT-prolongation and TdP cases associated with each study drug was calculated over time. Furthermore, for each case, dosage of the drug, withdrawal or discontinuation in the report, was recorded. **RESULTS:** A total of 5,088 reports were associated with QT prolongation and TdP were associated with SSRI drugs over the 14-year study period. Only 18% (219) of the adverse event reports were related specifically to citalopram, while the rest were related to other SSRI drugs. There were 1,102 reports for women and 727 for men and 202 wereander gender information. The rate of QT prolongation and TdP associated with dosages of 20 mg, 40 mg, and 60 mg of citalopram per day were 39%, 21%, and 2%, respectively. **CONCLUSIONS:** Citalopram is still in use without dosage withdrawal. So we were unable to draw any conclusions regarding dosage-related events. **RESULTS:** The conclusions confirmed an association between the use of citalopram with QT prolongation and TdP. Furthermore, the association was not limited to citalopram alone but was widespread across the SSRIs. There were more adverse events observed for women than for men. The gender dependency was not established in this study. Future studies are warranted.