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USAGE AND PERSISTENCY OF ATYPICAL ANTI-PsyCHOTICS IN THE TREATMENT OF SCHIZOPHRENIA

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OBJECTIVES: To evaluate usage and persistency of atypical anti-psychotics among schizophrenia patients utilizing a managed care database. METHODS: A retrospective study utilizing the Pharmetrics claims database was conducted. All patients with a diagnosis of schizophrenia (ICD 9 codes 295.9 to 295.9) in 2003 were included in the analysis. Patients were required to have a minimum 12 months of continuous eligibility following their index diagnosis. A subset of patients was classified on the basis of first atypical anti-psychotic mono-therapy treatment (Risperidone, Olanzapine, Quetiapine, Aripiprazole or Ziprasdone). Persistency (%) in this group was calculated by following a closed cohort of patients on a specific atypical anti-psychotic from month one to month 12. Patients who dropped-off therapy and then re-initiated the same atypical agent within the 12 month period (re-starts) were included in the analysis. RESULTS: A total of 6418 patients were analyzed. Of these 60.4% were currently on an antipsychotic (typical/atypical) treatment. Atypical mono-therapy including clozapine was used by 51.7%, combination atypical therapy by 30.5%; the remaining 17.8% of the currently treated cohort were on typical antipsychotics. The subset of 1777 patients on atypical monotherapy consisted of 668 (37.6%) Risperidone; 754 (42.4%) Olanzapine; 228 (12.8%) Quetiapine; 105 (5.9%) Ziprasidone. Aripiprazole patients (n=24) were excluded from this analysis. Olanzapine and Risperidone patients were more persistent (60% and 59%) compared to Quetiapine (44%) and Ziprasidone (40%). CONCLUSION: Majority of schizophrenia patients are currently treated with atypical anti-psychotics with Olanzapine and Risperidone in the lead in terms of treatment share and persistency.

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ADHERENCE AND SWITCHING WITH ANTIDEPRESSANTS

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OBJECTIVES: The purpose of this study was to quantify the extent of non-adherence across antidepressants and to determine the rate of switching within the class. METHODS: Blinded prescription data from two national retail pharmacy chains was analyzed for 417,002 patients taking sertraline, venlafaxine, paroxetine, and escitalopram. Cumulative drug consumption (total days supply) during the one year follow up period was employed as the measure of adherence. Kaplan Meier estimates of survival (persistency) curves were used to assess the time to discontinuation and to calculate the one year rate of discontinuation. Baseline patient characteristics, including age, gender, geographic region, median income, index quantity dispensed, population density, co-pay, and index refill and days supply prescribed were analyzed. RESULTS: Adherence data across these antidepressants showed that escitalopram patients obtained the fewest days of medication (161.26), and venlafaxine patients had the greatest number of days of therapy (191.54). At day 30, 30% of venlafaxine patients, 34% of sertraline patients, and 40% of paroxetine and escitalopram patients discontinued therapy. After 6 months, 60% of venlafaxine patients, 64% of sertraline patients, 68% of paroxetine patients, and 70% of escitalopram patients discontinued therapy. The rate of switching to another agent was 3.67% for paroxetine, 3.14% for venlafaxine, 2.95% for escitalopram, and 2.1% for sertraline. CONCLUSION: Even though antidepressant medications are effective in controlling depression, their effectiveness is reduced by the lack of adherence to therapy. Adherence can vary significantly across the agents within a class. Efforts to maintain patients on antidepressant therapy at the initiation of treatment are needed and most likely will affect future adherence.

PMH54

PRELIMINARY VALIDATION OF THE ENGLISH VERSION OF THE SCHIZOPHRENIA QUALITY OF LIFE (S-QoL) SCALE

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OBJECTIVES: This study assesses the validity and responsiveness over changes of the English version of the S-QoL, first schizophrenia-specific health-related quality of life scale developed from patients’ viewpoint on the need-based framework. METHODS: The S-QoL, comprising 41 items exploring eight dimensions (Psychological Well-being, Self-esteem, Relations with Family, Relations with Friends, Resilience, Physical Well-being, Autonomy and Sentimental Life), was first developed and validated in French. After a standard backward-forward translation process, its English version was tested in a sample of patients with schizophrenia. Two assessments were performed: baseline and 12 weeks later. Psychometric properties (validity and sensitivity over changes) were evaluated using methods from Classical Test Theory, Rasch analyses and structural equation modelling. RESULTS: A total of 128 patients filled-in the S-QoL. The factorial structure of the original version was globally retrieved. The questionnaire was well accepted (missing dimension rates lower than 3%). Cronbach’s alphas were greater than 0.70 for 6 of the 8 dimensions. The S-QoL dimensions and total score were statistically correlated with depression assessed with the Calgary Depression Scale for Schizophrenia (CDSS), and severity of symptoms measured by the Positive and Negative Symptoms Scale (PANSS). Using the sub-sample of patients rated “Very much Improved” or “Improved” on the Clinical Global Impression of Improvement (CGI-I) at Week 12, all the dimensions and the total score were statistically significantly improved. Five of the dimensions, as well as the total score, reached an effect size of at least 0.50 indicating an at least moderate change on health status. CONCLUSION: These results strengthen the usefulness of assessing the impact of schizophrenia on patients’ everyday life with the S-QoL, specifically designed for assessing the health-related quality of life of patients with schizophrenia. Its sensitivity to changes in health state is of major interest for evaluative purposes.

PMH55

DEVELOPMENT AND VALIDATION OF THE SLEEP IMPACT SCALE FOR INSOMNIA

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OBJECTIVES: The objectives were to develop and validate a sleep-specific patient-reported outcomes instrument in US-English and US-Spanish that can be used in clinical trials. METHODS: In the development phase, interviews were conducted with 25 US-English speaking participants suffering from insomnia. Participants’ comments were reviewed by two US-Spanish speakers to ensure commonality. Item generation was conducted simultaneously in the two languages to ensure conceptual equivalence. The face and content validity of the newly developed instrument (Sleep Impact Scale [SIS]) was tested in 10
US-English speaking and 16 US-Spanish speaking participants with primary or secondary insomnia. Data for the validation of the SIS were collected alongside a North American 4-week multicenter, double-blind, placebo-controlled, randomized, parallel-group study in primary and secondary insomnia patients. Item level analyses including assessment of missing data, item-item correlations, Principal Components Analysis, and clinical validity were conducted. Items with floor or ceiling effects were candidates for deletion, as were items which did not load with any particular domain. Once domains were determined, validity of the domains was assessed through internal consistency reliability, item-domain concurrent and divergent validity, clinical validity, concurrent validity and confirmatory factor analysis. Additionally, responsiveness and minimal important difference estimates were determined.

RESULTS: Patient interviews resulted in 55 items in 8 domains. During item reduction and validation, 18 items were deleted based on their content validity, high ceiling effect (>40%), redundancy (Inter-item Pearson correlation > 0.80) no or multifactor loading and/or failure to meet the Item-level discriminant validity criterion. After reduction, the final SIS consists of 35 items in 7 domains.

CONCLUSION: The SIS was developed to account for US-English and US-Spanish cultural differences. The validation study provides evidence on the psychometric properties of the SIS. The SIS has been shown to adequately meet the criteria for a validated measure to be used in clinical trials.

A REVIEW OF INSTRUMENTS USED TO ASSESS THE IMPACT OF ALCOHOLISM ON QUALITY OF LIFE
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OBJECTIVES: To comprehensively explore existing quality of life (QoL) measures in alcoholism (alcohol abuse and alcohol dependence).

METHODS: Systematic searches of Scopus (1990–2007) were conducted using terms synonymous with alcoholism combined with terms associated with measuring QoL.

RESULTS: In total, 618 abstracts were identified detailing the use of 16 generic patient-reported measures to assess QoL in alcoholism. Upon further examination (ie searching Scopus using the QoL measure as a search term from date of development) nine measures of QoL were determined.

CONCLUSION: The authors have claimed to epitomise alcohol-related QoL. This study evaluated the benefits of a Psychosocial Intervention Program (PIP) on caregivers’ burden.

IMPROVED SLEEP IMPACT IN GENERALIZED ANXIETY DISORDER WITH ZOLPIDEM TARTRATE EXTENDED-RELEASE
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OBJECTIVES: Insomnia is frequently associated with generalized anxiety disorder (GAD) and affects the patient’s day to day life. The Sleep Impact Scale (SIS) was developed to assess the impact of insomnia; however it has not been used in GAD. Therefore, a study was conducted to validate the SIS and evaluate the impact of zolpidem tartrate extended-release on insomnia in GAD.

METHODS: Validation and efficacy data of the SIS were collected alongside a randomized, placebo-controlled trial of escitalopram + placebo or zolpidem tartrate extended-release in adults with insomnia associated with GAD. The validation consisted of evaluation of the validity and reliability, the responsiveness and the MID of the SIS domains to ensure the questionnaire was acceptable in a GAD population. The efficacy analysis was performed on the ITT population, consisting of general linear models to evaluate changes from baseline at each timepoint, with study endpoint as the primary change score analysis. Longitudinal analyses were also performed to evaluate the effects of