Risperidone Long Acting Injection (RLAI) in the Treatment of Early Versus Late Diagnosis Patients with Schizophrenia: Interim Results from Observational Studies Conducted in Spain, Australia and Belgium

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OBJECTIVES: To compare 12-month psychiatrist-related hospitalization pre and post-RLAI therapy and clinical outcomes in early (<5-years) versus late (>5-years) diagnosis outpatients with schizophrenia from e-STAR in Spain (SP), Australia (AU), and Belgium (BE). METHODS: E-STAR is a secure, web-based, international, long-term observational study of patients with schizophrenia who commence RLAI treatment. Data are collected both retrospectively and prospectively and include hospitalisations and clinical outcomes that were evaluated using the Clinical Global Impression Severity Scale (CGI-S) and Global Assessment of Functioning Scale (GAF). RESULTS: Overall, 714 patients (SP = 393, AU = 249, BE = 72) were included. Twenty-two percent were classified as early diagnosis. Average time since diagnosis was 2 and 15.9 years in the early and late diagnosis group, respectively. Patients in the early diagnosis group were significantly younger than those in the late diagnosis group (32.2 vs. 41.7, p < 0.001). Both groups experienced a significant decrease in the number of hospitalizations per patient in the 12-month post versus the 12-month pre-RLAI period (early = 0.77 to 0.36, p < 0.001; late = 0.54 to 0.43, p = 0.004). Reduction in hospitalization rates per patient from the pre and post-RLAI period was significantly greater in the early diagnosis group (early = −0.4, late = −0.11, p = 0.006). The average length of stay (in days) decreased for both groups but it was only statistically significant in the early diagnosis group (early = 21.2 to 12.4, p = 0.041; late = 15.6 to 13.6, p = 0.40). Both groups experienced significant improvements in GAF and CGI-S scores. However, the early diagnosis group experienced greater improvements in GAF and significantly greater improvements in CGI (GAF: early = +14.1, late = +12.5, p = 0.30; CGI: early = −1.04, late = −0.76, p = 0.017). CONCLUSION: This interim analysis suggests that treatment with RLAI result in better outcomes in patients with schizophrenia who have been diagnosed for less than five-years than those diagnosed for five or more years.

Mental Health—Patient-Reported Outcomes

Switching of Antipsychotics Among Stable and Unstable Schizophrenia Patients

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OBJECTIVES: To assess switching of atypical and typical antipsychotics among stable and unstable patients and the relationship between switching and hospitalization. METHODS: We used data from the first year of a large (N = 2327), 3-year non-interventional observational study of schizophrenia patients in the U.S. conducted between 7/1997 and 9/2003. Participants with at least one prescription for any antipsychotic were included in this analysis. Participants were defined as “stable” if they had PANSS total scores below 70 at enrollment and no psychiatric hospitalization, psychiatric emergency services, suicide attempt, or arrest in the 1–6 months prior to enrollment. All other participants were deemed “unstable.” Systematic medical record abstraction provided antipsychotic prescription information. The stable and unstable patient groups were compared on antipsychotic switching rates (switch from the antipsychotic used at enrollment) and on antipsychotic augmentation. Group comparisons were performed using t-tests for continuous variables and Chi-square tests for categorical variables. RESULTS: Of 2158 participants, 59.6% were deemed unstable and 40.4% were considered stable. Unstable patients were more likely to experience switching and augmentation of antipsychotics. Typical antipsychotics were more likely to be used as augmentors (58.7%, p < 0.001), whereas atypical antipsychotics, especially olanzapine, were more likely the medications to be switched to (61.9%, p < 0.001). A significantly higher proportion of switchers (44.6%) than non-switchers (17.9%, p < 0.001) were hospitalized for psychiatric purposes during the 1-year observation period. Among switchers who were hospitalized at any time during the 1-year period, 52.4% switched medication during hospitalization, 29.8% switched prior to hospitalization, and 17.8% switched post hospitalization. CONCLUSION: Switching of antipsychotics appears to be significantly associated with unstable, more severe illness profile and with psychiatric hospitalizations. Atypical antipsychotics are more likely the medications to be switched to. Finding an effective treatment option...
that stabilizes the disease and reduces hospitalizations will help patients and payers as well.

PMH44

THE PREDICTIVE VALIDITY OF DIFFERENT ADHERENCE MEASURES USING ADMINISTRATIVE CLAIMS DATA
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OBJECTIVES: To determine the predictive validity of eight different adherence measures by studying the variability explained between each measure and two outcome measures: hospitalization episodes and total non-pharmacy cost. METHODS: This study was a retrospective analysis of the Arkansas Medicaid administrative claims data. Schizophrenia (ICD-9-CM = 295.**) patients were identified in the recruitment period July 2000 through April 2004. Patients had to be >18 years old, have prescription benefits, and continuously eligible for 6 months prior and 24 months after their first antipsychotic prescription. Persons taking two different antipsychotic drug products simultaneously were excluded. Medication Possession Ratio (MPR), Proportion Of days Covered (PDC), Medication Possession Ratio, modified (MPRm), Refill Compliance Rate (RCR), Compliance Ratio (CR), Continuous Measure of Medication Gaps (CMG), Days Between Fills Adherence Rate (DBR), and Continuous, Single Interval Measure of Medication Acquisition (CSA) were computed and modeled to predict hospitalizations and non-pharmacy costs. RESULTS: A total of 3971 patients with a mean age 46.5 years, 54% were female, 55% were white, and 38% were black. The one-year adherence rates were numerically similar for MPR (0.74 SD = 0.29), MPRm (82.21%, SD = 64.18), DBR (0.72, SD = 0.29), and CSA (0.95 SD = 0.79) had higher adherence values. The partial R-squares of the multivariate regression models will be reported. CONCLUSION: There is considerable variability in rates of adherence among the 8 measures of adherence. MPR and PDC which used the entire study period as the denominator had the most conservative adherence values. In contrast MPRm, PDC, RCR, CR, DBR which only consider the time between first and last prescription fill dates estimate higher levels of adherence.

SOCIODEMOGRAPHIC AND CLINICAL CORRELATES OF USEFULITY SCOR ES IN ALZHEIMERS DISEASE
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OBJECTIVES: The pharmaco-economic evaluation of treatment for Alzheimer’s Disease (AD) has relied on general measures of utilities that have been validated in general populations. There has been little study of the relationship between disease specific measures of health status, functional capacity and/or quality of life in AD and measures of Quality Adjusted Life Years (QALYs), the outcome of primary interest in pharmaco-economic assessments. METHODS: Follow-up data were obtained from caregiver proxy raters at 3, 6, and 9 months concerning 421 patients with early stage Alzheimers Disease, living with at least one caregiver in a non-institutional setting, who participated in the CATIE AD trial of antipsychotic medication for psychosis or aggression due to AD. Multiple regression models were used to examine the relationship between change in the Health Utilities Index (HUI)—Mark III, and a broad range of socio-demographic characteristics, psychiatric symptoms, cognitive performance, activities of daily living, and AD-related quality of life—to determine the measures that were most strongly related to QALYs and the power of clinical measures to predict utility scores. RESULTS: Analysis of correlates of change in utilities scores from baseline showed weak bivariate, and for the most part, non-significant multivariate relationships between change in health utility scores and measures of socio-demographic characteristics, psychiatric symptoms, and cognitive performance. However, there were highly significant associations between decreases in health utilities and change two scales: the AD Cooperative Study Scale for Activities of Daily Living (ADCS-ADL) and AD-Related Quality of Life (AD-RQOL) (both p < 0.001). The total R-squared was 17%. CONCLUSION: Only weak relationships were found between changes in a standard measure of health utilities and socio-demographic and clinical indicators. The presence of significant cognitive impairment and the need to rely on proxy raters may limit the validity of utility measurement in AD.

PMH45

NOVEL USE OF A TELEPHONE BASED INTERACTIVE VOICE RESPONSE SYSTEM TO IMPROVE DATA COLLECTION
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OBJECTIVES: To investigate whether electronic memory aids and IVR verbal numeric scales improve the quality of data collection methods. To evaluate whether perceptions of clinical change reported directly by the patient is enhanced by the use of a novel telephone based interactive voice response system. METHODS: A total of 137 patients from a multi-site, double-blind, placebo controlled study were administered the IVR PGI-I and the Memory Enhanced Retrospective Evaluation of Treatment (MERET) over a 4-week period. Effect sizes using these approaches were determined and compared to determine any differences. In addition, we investigated whether dosage level predicted a more rapid onset of action. RESULTS: At 2 and 4 weeks the point estimates for both IVR PGI-I and MERET were 2.68 and 3.24 (p = 0.035) and 2.5 and 3.21 (p = 0.015), respectively. Overall, the effect size for the PGI-I was 0.526 compared to 0.612 for MERET. For the subjects in the higher dose group, there were significant improvements reported by the patient at 1 day for shoulder (p = 0.008) and back pain (p = 0.01). Significant differences were also found at day 3 for pain while awake (p = 0.03), day 5 for Global emotional improvement (p = 0.03), and day 7 and Global physical improvement (p = 0.04) at day 7. No other significant differences were found. CONCLUSION: The use of an electronic memory aid produced a 16.3% larger drug-placebo treatment effect size compared to the standard PGI-I. MERET ratings increased the patients’ perception on the effectiveness of active drug treatment with minimal influence of the placebo effect. In this study, the higher dose had an earlier onset of efficacy for both physical and emotional symptoms. The daily IVR reporting of this data allowed detection of a rapid onset of action.

PMH47

THE EFFECTS OF PATIENT TYPE ON PHYSICAL AND MENTAL HEALTH OF CAREGIVERS IN FRANCE, GERMANY, ITALY, SPAIN AND THE UNITED KINGDOM
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OBJECTIVES: To assess the effects of caring for adult patients with chronic conditions on the physical and mental health of caregivers. METHODS: This analysis was based on data from