Abstracts

The initial examination of the LPS-A subscale suggested low diabetes self-care scores and high ADHD symptom scores were associated with worse HbA1c values. CONCLUSIONS: These findings suggest that the occurrence of T2DM and ADHD symptoms could result in poor HbA1c management and may lead to increased resource utilization.

The validation of Turkish version of Personal and Social Performance Scale (PSP)

Method: The study was performed in the psychiatry departments of two university hospitals. In- or outpatients diagnosed as schizophrenia or bipolar disorder were included in the study. Exclusion criteria consisted of comorbidity of other psychiatric disorders (including substance use disorders) and physical diseases. For concurrent validity, besides PSP, Clinical Global Impression (CGI), Global Assessment of Functioning (GAF) of DSM-IV, Quality of Life and Satisfaction Questionnaire (QLS-Q), and Positive and Negative Schizophrenia Scale (PANSS) were used. For discriminant validity, the scores of 100 patients with and without significant remission were compared. Results: The study was carried out with a total of 135 patients, 105 (77.8%) diagnosed as schizophrenia and 30 (22.2%) diagnosed as bipolar disorder. The mean age of the patients was 34.1 ± 10.7 and 75 (53.6%) of them were male. The duration of illness was 10.4 ± 7.5 years. The mean score of PSP in the relapse analysis, the Cronbach alpha coefficient was 0.8327, and item-total score correlations were between 0.4920-0.7462. In the validity analyses, the total score of PSP was significantly correlated with the total score of CGI (r = 0.854, p < 0.0001), GAF (r = 0.746, p < 0.0001), QLS-Q (r = 0.734, p < 0.0001), and PANSS (r = 0.664, p < 0.0001). The difference between the patients with and without significant remission was significant (54.8 ± 14.4 vs. 72.6 ± 9.8, t = 7.434, p < 0.0001). CONCLUSION: The Turkish version of PSP was found to be reliable and valid in severe mental disorders. It can be used both in clinical trials and routine follow-up.

Psychometric properties of the life participation scale for adults as assessment deficits in adaptive functioning

Saghir KE, Kurton V, Khan SA

Neuroscience, Inc, Hendos, VA, USA, ‘13 Research, Cary, NC, USA, ‘13 Lilly and Company, Indianapolis, IN, USA

Objective: The Life Participation Scale for Children was designed to measure treatment-related improvements in adaptive functioning in children with ADHD. To measure these attributes in adult subjects, we developed a Life Participation Scale for Adults (LPS-A). METHODS: LPS-A items were selected by convening focus groups, interviewing experts, and performing structured cognitive interviews to improve item wording. These were administered in a 2-week study of treated (N = 10) and untreated (N = 10) participants with ADHD and normal controls (N = 11). Cronbach’s alpha, Lin’s concordance correlation, and Pearson’s correlations were used to assess internal consistency, test-retest reliability, and convergent/divergent validity. LPS-A scores were compared for ADHD/control, treated and untreated, and less/more severe participants to measure discriminant validity. RESULTS: The LPS-A demonstrated internal consistency (Cronbach’s alpha = 0.92–0.96). Concordance correlations indicated test-retest reliability (r = 0.79 to 0.86). Convergent, divergent, and discriminant validity were demonstrated. CONCLUSIONS: The initial examination of the LPS-A suggests accepta-ble levels of validity and reliability. Larger studies will provide further information about the psychometric properties of the LPS-A. The LPS-A appears to be a promising new instrument for measuring adaptive function in adults with ADHD.

Evaluating central nervous system drug labels for patients-reported outcomes claims

Vasudevan L, Gennarelli EK, Bharat M

Quintiles, Inc, Falls Church, VA, USA

Objective: Previous studies (prior to 2003) have suggested that central nervous system (CNS) drugs have had the highest number of patient-reported outcomes (PRO) claims used in product approvals. This study examined the use of PRO as efficacy endpoints in label claims of recent FDA-approved CNS drugs between 2003 and 2008. METHODS: Product labels of FDA-approved prescription-only New Molecular Entities (NMEs) from the CNS drug category between January 2003 and October 2008 were reviewed. The most recent product label, obtained either from the FDA’s Center for Drug Evaluation and Research (CDER) or directly from the company website, was used for all the drugs, including the drugs withdrawn from the market. Efficacy endpoint data was obtained from the Clinical Studies section of the approved product label. Efficacy measures were categorized into PRO, clinician-reported outcomes (CRO), or both. RESULTS: During the five-year study period of 2003-2008, FDA-approved NMEs were CNS agents. The CNS agents included four drugs for neuromuscular disorders, two antidepressants, two sedatives, one smoking cessation drug, one analgesic, one CNS stimulant, and one drug treating alcoholics for illness or use measures in the CNS product labels, seven (23%) were PRO. The four drugs using PRO endpoints included one antidepressant, one analgesic, one CNS stimulant and one smoking cessation drug. Of the seven PRO used, three were symptom scales, two were global impression scales, one scale measured cortisol, and one scale measured functional impairment. The percentage of approved CNS drugs using PRO as efficacy endpoints in label claims declined since 2002 (2003-08: 28.5%; 1997-2002: 75%). CONCLUSION: The latter half of the past decade has seen a considerable decrease in the number of CNS drugs that have had PRO-based label claims. Symptoms scales are the prominent type of PRO used in CNS drug label claims.