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Efficacy and safety of generic escitalopram (Lexacure) in patients with major depressive disorder: A 6-week, multi-center, randomized, rater-blinded, escitalopram-comparative, non-inferiority study

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Objectives The primary aim of this non-inferiority study was to investigate the clinical effectiveness and safety of generic escitalopram (Lexacure) versus branded escitalopram (Lexapro) for patients with major depressive disorder (MDD).

Methods The present study included 158 patients who were randomized (1:1) to receive a flexible dose of generic escitalopram ($n=78$) or branded escitalopram ($n=80$) over a 6-week single-blind treatment period. The clinical benefits in the two groups were evaluated using the Montgomery–Åsberg Depression Rating Scale (MADRS), the 17-item Hamilton Depression Rating Scale (HDRS), the Clinical Global Impressions-Severity Scale (CGI-S), and the Clinical Global Impressions-Improvement Scale (CGI-I) at baseline, week 1, week 2, week 4, and week 6. The frequency of adverse events (AEs) was also assessed to determine safety at each follow-up visit.

Results At week 6, 28 patients (57.1%) in the generic escitalopram group and 35 patients (67.3%) in the branded escitalopram group had responded to treatment ($P=0.126$), and the remission rates (MADRS score: ≤ 10) were 42.9% ($n=21$) in generic escitalopram group and 53.8% ($n=28$) in the branded escitalopram group ($P=0.135$). The most frequently reported AEs were nausea (17.9%) in the generic escitalopram group and nausea (20.0%) in the branded escitalopram group.

Conclusions The present non-inferiority study demonstrated that generic escitalopram is a safe and effective initial treatment for patients with MDD and may also be considered as an additional therapeutic option for this population.

Disclosure of interest The authors have not supplied their declaration of competing interest.

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Characteristics and treatment patterns of children and adolescents with attention-deficit/hyperactivity disorder in real-world practice settings

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Objective To document patient characteristics and treatment patterns in a real-world population diagnosed with attention-deficit/hyperactivity disorder (ADHD).

Methods This was a retrospective chart review of children/adolescents (6–17 years) diagnosed with ADHD in the UK, Germany and Netherlands who initiated stimulant monotherapy (SM), non-stimulant (atomoxetine) monotherapy (NSM) or polypharmacy (SM/NSM \pm SM/NSM or other psychotropics) on/after 1-1-2012. To facilitate descriptive comparisons, cohort quotas were imposed: $\sim 50\%$ SM; $\sim 25\%$ NSM; $\sim 25\%$ polypharmacy. Index date was first SM, NSM or polypharmacy treatment on/after 1-1-2012. Patients were required to have ≥ 6 months' pre-index (baseline) history and ≥ 12 months' post-index follow-up. Analyses were descriptive.

Results In total, 497 patients were included (mean [SD] age: 10.8 [2.9] years; 77% male); 65% (SM), 63% (NSM) and 83% (polypharmacy) had at least marked baseline ADHD severity based on Clinical Global Impressions scale ($P < 0.05$ SM/NSM vs polypharmacy). Ninety percent (SM), 75% (NSM) and 73% (polypharmacy) were pharmacotherapy naïve at index (all $P < 0.10$); 61% (SM), 65% (NSM) and 72% (polypharmacy) received previous behavioural therapy. In SM patients, methylphenidate was predominant (most frequent brands: Concerta® [29%], Medikinet® [28%]); in polypharmacy patients, methylphenidate plus atomoxetine (22%) or other psychotropic (19%) was most common. Index therapy switch was common, particularly in polypharmacy patients (25%) ($P < 0.05$ vs SM [14%] and NSM [13%]). Switches were precipitated by poor response in 75% of cases overall.

Conclusions Polypharmacy patients generally presented a more complicated history (including higher ADHD severity) and treatment pathway versus monotherapy patients. Index therapy switches were commonplace and more frequent in polypharmacy patients, often due to poor response.

Disclosure of interest The authors have not supplied their declaration of competing interest.

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Sexual side effects in patients treated with desvenlafaxine: An observational study in daily practice

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Introduction Sexual function is important for patients' well-being but it is a common side effect of SSRI and SNRI, included desvenlafaxine.

Objectives and aims Evaluate incidence and characteristics of sexual dysfunction caused by desvenlafaxine in the clinical practice.

Methods One hundred and thirty-three patients with recently introduced desvenlafaxine treatment are recruited from Barakaldo and Uribe-Kosta Mental Health Centres in Biscay, Spain. UKU scale is administered to measure sexual side effects. Statistical analysis is performed using SPSS v.22.