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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

J.H. Jeong[1], W.M. Bahk[2,*], Y.S. Woo[2], K.U. Lee[3], M.D. Kim[4], W. Kim[5], J.C. Yang[6], K.H. Lee[7], S.Y. Lee[8]
[1] *St. Vincent's Hospital, psychiatry, Suwon, Republic of Korea*
[2] *Yeouido St. Mary's Hospital, psychiatry, Seoul, Republic of Korea*
[3] *Uijeongbu St. Mary's Hospital, psychiatry, Uijeongbu, Republic of Korea*
[4] *College of Medicine, Jeju National University, psychiatry, Jeju, Republic of Korea*
[5] *Seoul Paik Hospital, psychiatry, Seoul, Republic of Korea*
[6] *Chonbuk National University Medical School, psychiatry, Jeonju, Republic of Korea*
[7] *College of Medicine, Dongguk University, psychiatry, Seoul, Republic of Korea*
[8] *Wonkwang University School of Medicine, psychiatry, Iksan, Republic of Korea*
* *Corresponding author.*

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

A. Joseph[1], K. Davis[2], M. Fridman[3], P. Gustafsson[4,*], J. Quintero[5], V. Sikirica[6], T. Banaschewski[7]
[1] *Shire, Global HEOR and Epidemiology, Zug, Switzerland*
[2] *RTI Health Solutions, Health Economics, Research Triangle Park, USA*
[3] *AMF Consulting Inc., Health Economics, Los Angeles, USA*
[4] *Linköping University, Department of Clinical and Experimental Medicine and Department of Child and Adolescent Psychiatry, Linköping, Sweden*
[5] *Hosp. University Infanta Leonor, Psychiatry Department, Madrid, Spain*
[6] *Shire, Global HEOR and Epidemiology, Wayne, USA*
[7] *Central Institute of Mental Health, Department of Child and Adolescent Psychiatry and Psychotherapy, Mannheim, Germany*
* *Corresponding author.*

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 ± SM/NSM or other psychotropics) on/after 1-1-2012. To facilitate descriptive comparisons, cohort quotas were imposed: ~50% SM; ~25% NSM; ~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.
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Sexual side effects in patients treated with desvenlafaxine: An observational study in daily practice

B. Navarro[1,*], L. Perez[1], L. Erkoreka[1], A. Arroita[2], I. Perez[3]
[1] *Red de Salud Mental de Bizkaia, CSM Barakaldo, Bilbao, Spain*
[2] *Re de Salud Mental de Bizkaia, CSM Barakaldo, Bilbao, Spain*
[3] *Hospital Universitario Cruces, psiquiatría, Barakaldo, Spain*
* *Corresponding author.*

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 Barakldo 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.

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Results Sexual dysfunction is observed in 5 patients (3.7%) at 50 and 100 mg/d (2 and 3 patients, respectively) desvenlafaxine doses. Two patients (1.5%) have experimented more than one sexual side effect. Regarding gender differences, the most frequent sexual dysfunctions are diminished sexual desire (5.5%) and erectile dysfunction (5.5%) in men and orgasmic dysfunction (1.2%) in women (*P*-values are 0.034; 0.034 and 0.408, respectively). Discontinuation is decided in 60% of patients.
Conclusions Desvenlafaxine has a well-tolerated sexual side effect profile in general population. There are some gender-related differences both in presentation and perception, as it has been described with other drugs, and this should be taken into account by prescriptors.
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The novel antipsychotic cariprazine (RGH-188): State-of-the-art in the treatment of psychiatric disorders

L. Orsolini [1,2,3,4,*], A. Valchera [4,5], D. De Berardis [4,6,7], R. Vecchiotti [1,2,4], F. Iasevoli [8]
[1] *Villa San Giuseppe Hospital, Hermanas Hospitalarias, Department of Psychiatry, Ascoli Piceno, Italy*
[2] *Maastricht University, Department of Psychiatry and Neuropsychology, Maastricht, Italy*
[3] *University of Hertfordshire, Department of Pharmacy, School of Life and Medical Sciences, Hatfield, United Kingdom*
[4] *Polyedra, Polyedra Research, Teramo, Italy*
[5] *Villa San Giuseppe Hospital, Heramanas Hospitalarias, Department of Psychiatry, Ascoli Piceno, Italy*
[6] *Hospital "G. Mazzini", ASL 4, NHS, Department of Mental Health, Psychiatric Service of Diagnosis and Treatment, Teramo, Italy*
[7] *University of "G. D'Annunzio", Department of Neuroscience, Imaging and Clinical Science, Chieti, Italy*
[8] *Laboratory of Molecular Psychiatry and Psychopharmacotherapeutics, Section of Psychiatry, Department of Neuroscience, University School of Medicine "Federico II", Naples, Italy*
* *Corresponding author.*

Introduction Cariprazine (RGH-188) is a novel antipsychotic drug that exerts partial agonism of dopamine D_2/D_3 receptors with preferential binding to D_3 receptor, antagonism of $5HT_{2B}$ receptors and partial agonism of $5HT_{1A}$. Currently, cariprazine is in late-stage clinical development (phase III clinical trials) in patients with schizophrenia (S) and in patients with bipolar disorder (BD), as well as an adjunctive treatment in patients with Major Depressive Disorder (MDD) and drug-resistant MDD.
Objectives Cariprazine has completed phase III trials for the acute treatment of schizophrenia and bipolar mania, phase II trials for the bipolar depression and MDD whilst it is undergoing phase III trials as an adjunct to antidepressants.
Aims The present review aims at proving a comprehensive summary of the current evidence on the safety, tolerability and efficacy of cariprazine in the treatment of schizophrenia, BD (manic/mixed/depressive episode) and MDD.
Methods A systematic search was conducted on PubMed/Medline/Scopus and the database on Clinical Trials from inception until April 2015 by typing a set of specified keywords.
Results Available evidence seems to support cariprazine efficacy in the treatment of cognitive and negative symptoms of schizophrenia. Preliminary findings suggest its antimanic activity whilst it is still under investigation its efficacy in the treatment of bipolar depression and MDD. Furthermore, the available data seems not to allow judgements about its antipsychotic potential in comparison with currently prescribed antipsychotics.
Conclusions Further studies should be carried out to better investigate its pharmacodynamic and clinical potential, particularly as alternative to current antipsychotic drugs.
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Use of inhaled loxapine in acute psychiatric agitation

S. Ovejero [1,*], M. Iza [1], S. Vallejo [1], C. Vera [1], A. Sedano [1], R. Álvarez [2], L. Mata [1], S. Sánchez-Alonso [1]
[1] *Hospital Universitario Fundación Jiménez Díaz, Psychiatry, Madrid, Spain*
[2] *Hospital Universitario Rey Juan Carlos, Psychiatry, Móstoles, Spain*
* *Corresponding author.*

Objectives The aim of this work is to study the efficacy of loxapine inhalation powder on agitated patients in a psychiatric inpatient unit.
Methods Nineteen patients sample, with an average age of 39.4 years old, diagnosed with schizophrenia, bipolar disorder or schizoaffective disorder. Patients inhaled loxapine 10 mg, using the staccato system, when they suffered a psychomotor agitation. The clinical efficacy was measured as a change from baseline in the Positive and Negative Syndrome Scale-Excited Component (PANSS-EC) and in the Young Mania Rating Scale (YMRS) one hour after the administration of loxapine.
Results A mean of 9.8 points reduction (22.6 at baseline and 12.7 one hour after the administration) was found on the PANSS-EC (*t*-test, $P < .001$) and 68.4% of the patients were considered responders as they obtained a reduction of at least 40% of the basal score. On 10 of the total of the agitated patients showed an improvement of the psychomotor excitement, and this allowed the clinicians to remove the physical restraint; on 6 of the agitated patients the physical restraint could be avoided during the whole treatment; and 3 of the patients experienced a reduction of the excitement. The reduction on PANNS-EC on the latest group was not statistically significant (*t*-test, $P = .121$).
Conclusions Inhaled loxapine was a non-invasive, rapid and effective alternative treatment for acute agitation in a psychiatric inpatient unit. It resulted more effective on mild and moderate cases; not been significantly effective on the severe cases of agitation.
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Which antidepressants are associated with increased risk of developing mania? A retrospective electronic case register cohort study

R. Patel [1,*], P. Reiss [1], H. Shetty [2], M. Broadbent [2], R. Stewart [3], P. McGuire [1], M. Taylor [1]
[1] *Institute of Psychiatry, Psychology and Neuroscience, Department of Psychosis Studies, London, United Kingdom*
[2] *South London and Maudsley NHS Foundation Trust, Biomedical Research Centre Nucleus, London, United Kingdom*
[3] *Institute of Psychiatry, Psychology and Neuroscience, Department of Psychological Medicine, London, United Kingdom*
* *Corresponding author.*

Introduction The symptoms of bipolar disorder are sometimes misrecognised for unipolar depression and inappropriately treated with antidepressants. This may be associated with increased risk of