from 21 to 77 years and is characterized mainly by avermian-type cerebellar disorder, persistent extrapyramidal syndrome, brainstem dysfunction and dementia of varying severity. It can also result in apraxia of the body, changes in the coordination and balance, dysarthria, as well as intentional and kinetic cerebellar tremor, involuntary movements of orofacial dyskinesias or resting tremor. **Objectives:** The authors intend to review the relevant and current literature in order to extend the knowledge about this condition and find the best conducts for clinical practice.

Methods: Non-systematic literature review.

**Results:** Complications from the use of lithium known in the medical literature include mainly nephrotoxicity, endocrine alterations and neurotoxicity. The neurotoxic effects of lithium usually occur at high serum concentrations. However, they can also occur with lithium in the therapeutic range, and memory, attention and ataxia impairment may be some of the permanent sequelae. The etiopathogenesis is unclear, but demyelination has been detected in multiple brain regions, mainly in the cerebellum. The mechanism of lithium-induced cerebellar injury is believed to be mediated by the entry of calcium into the cells of this organ. The main factors that predispose to greater side effects and risk of toxicity are patients with decreased renal function, advanced age, use of diuretics, dementia, pregnancy, low sodium intake and physical illness with vomiting and/or diarrhea.

**Conclusions:** Lithium is a drug used mostly in affective disorders and given the narrow therapeutic window, it requires close monitoring in order to avoid side effects that can be permanent. In this way, it is important to review the factors that increase the lithium toxicity and make recommendations about it.

Disclosure of Interest: None Declared

We valuated retrospectively the days of hospitalization after the aripiprazole 400 mg TIS and the number of emergency room access, analyzing the "repository of AUSL della Romagna" and discharge letters and the "CURE" program of the Psychiatric Service of Rimini.

Results: We evaluated 24 patients from February 2021 to April 2023, 11 male (45,8%), 13 female (54,2%); average age 37,95, average lenght of stay in hospital was 11,75 days. 10 patients with diagnosis of psychosis/schizophrenia (41,7%), 6 patients with bipolar disorder (25%), 4 patients with personality disorder (16,6%), 2 patients with substance induced psychosi (8,3%), 1 patients with delusional disorder (4,2%), 1 patient with schizoaffective disorder (4,2%). 6 patients had the two-injection start regimen in 2021 (25%), 13 patients in 2022 (54,2), 5 patients in 2023 (20,8%); 20 patients did not have admission in hospital after the TIS (83,3%), 4 patients had 1 or more admission after the injection (16,7%). 3 patients (12,5%) had accesses in emergency-room after Abilify Maintena. 15 patients (62,5%) continue therapy; 9 patients (37,5%) had suspended the injection for drop-out or because of change of therapy not correlated at adverse effects (1 female patient had suspended treatment after the two-injections due to pregnancy). Just 1 patient that continue Abilify Maintena 400 mg had 2 accesses in the emergency-room.

**Conclusions:** The coadministration of 2 injections of 400 mg aripiprazole was not associated with safety concerns beyond those expected with a single-injection start regimen. From the study it appears that the long-acting therapy with Alibify Maintena 400 mg once-monthly helps to stabilize the patient to prevent hospitalization and accesses in emergency-room.

Disclosure of Interest: None Declared

### EPV0821

## Abilify Maintena 400 mg (aripiprazole once-monthly), two-injection start (TIS) regimen: the experience of the Psychiatric Unit (SPDC) of Rimini

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**Introduction:** The single-injection start regimen for aripiprazole once-monthly 400 mg (AOM 400) in patients with schizofrenia requires a single intramuscular injection in the gluteal or deltoid site and 14 days of concurrent oral therapy. Based on a population-pharmacokinetic model, the European Medicines Agency and Canada has recently approved a simplified starting strayegy of aripiprazole once a month with single-day regimen of two injections at separate gluteal and deltoid injection sites, together with a single 20 mg dose of oral aripiprazole on the 1<sup>st</sup> day.

**Objectives:** The aim of the study is to evaluate the two injection start (TIS) regimen in inpatients in the Psichiatric Unit (SPDC) of the Hospital of Rimini.

**Methods:** We retrospectively reviewed medical records of patients, from February 2021 to April 2023, that have more than 18 years, who received the newly approved 2-injection start regimen as part of their standard care, evaluating if exist changes in clinical indicators, safety and tolerability of this regimen.

#### **EPV0822**

Evaluating the Efficacy of Prucalopride, a 5-HT4 Agonist, in Managing Antipsychotic-Induced Constipation: A Prospective Randomized Controlled Trial Conducted at Chronic Psychiatric Rehabilitation Facilities on Corfu Island

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**Introduction:** Achieving successful stabilization in patients with mental disorders often requires the administration of multiple antipsychotic medications, with the increasing prevalence of clozapine in cases resistant to other treatments. Constipation emerges as a particularly troublesome side effect, gradually progressing into a chronic state of gastrointestinal dysfunction, often accompanied by recurrent episodes of paralytic ileus of varying severity. Prucalopride, a 5-HT4 agonist, selectively targets receptors within the intestinal system. This interaction induces muscular contractions and promotes chloride secretion. Literature suggest its potential efficacy in managing constipation induced by clozapine. In light of these observations, we designed and will conduct a randomized controlled trial to evaluate the effectiveness of prucalopride in alleviating constipation in patients who had

shown limited responsiveness to conventional laxatives or other conservative treatments

**Objectives:** The primary objective of this article is to present the methodology of a randomized control trial assessing the efficacy of prucalopride in the treatment of constipation among patients with mental disorders

**Methods:** The study will enroll 60 adult patients with mental disorders who will require more than two antipsychotic medications, including clozapine, for stabilization, and who will be experiencing constipation as a side effect

To ensure the validity of the study, the following additional inclusion criteria will be applied:

- Patients will have no severe acute medical conditions
- Patients will have no history of malignancy
- Patients will have no severe respiratory or cardiac diseases
- Patients will have negative results from an endoscopic evaluation of the large bowel, ruling out conditions such as irritable bowel syndrome, ischemic colitis, inflammatory bowel disease, or malignant neoplastic disease

Following the screening process, the patients will be randomly assigned to one of two treatment groups:

**Prucalopride Group:** Patients in this group will receive prucalopride for the treatment of refractory constipation

**Conservative Treatment Group:** Patients in this group will continue with conservative treatments. The treatment's success will be determined based on specific endpoints:

- Normalization of bowel movements, characterized by having more than five bowel movements per week
- Resolution of symptoms related to gastrointestinal dysfunction, including pain, bloating, defecation difficulties, and paralytic ileus

**Results:** Following the conclusion of the study, data from both groups will be meticulously collected and subjected to rigorous statistical analysis to identify differences in treatment outcomes between these two therapeutic approachs

**Conclusions:** The detailed findings will be presented in a forthcoming article

Disclosure of Interest: None Declared

#### **EPV0823**

# A case of delirium following treatment with low dose mirtazapine and pregabalin

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**Introduction:** Pregabalin is a gamma-aminobutyric acid analogue used for the treatment of neuropathic pain, partial-onset-seizures, fibromyalgia, and anxiety disorders. Mirtazapine is an atypical antidepressant used in major depression and often prescribed offlabel for insomnia. Delirium, an acute confusional state, is a very rare adverse reaction of both medications.

**Objectives:** We report a case of an elderly patient treated with low dose pregabalin and mirtazapine who developed drug-induced delirium which resolved rapidly upon withdrawal of both drugs

**Methods:** A 75-year-old woman was admitted for symptoms of anxiety, various bodily complaints (dysphagia, headache, tinnitus, weakness) and sleep-onset insomnia over the preceding 2 months. On admission, examination revealed an apparently anxious, uneasy and emotional looking patient. Mini mental state examination, as well as clock drawing and copying were normal, suggesting absence of cognitive impairment. Physical examination was unrevealing except for high blood pressure recordings (150/90 mmHg). Laboratory testing indicated creatinine at 1.19 mg/dl, with a creatinine clearance moderately decreased at 38 ml/min. Upon admission, she was placed on pregabalin 25 mg bid and mirtazapine 30 mg ¼ tablet qd.

**Results:** Three days after admission, pregabalin was increased to 25 mg tid. On the same day and about 2 hours after the night dose, the patient acutely developed delirium: she presented confusion, disorientation, incoherence, restlessness and deterioration of her anxiety. On physical examination she was afebrile with no hypertonia or ataxia. An urgent brain magnetic resonance imaging was grossly unrevealing. Pregabalin and mirtazapine were discontinued, as a drug-induced delirium was suspected. She received as a symptomatic treatment lorazepam progressively up to 4 mg qd. Symptoms of delirium resolved rapidly, and she was discharged days later with full functional recovery

**Conclusions:** Cases of delirium have been described following treatment with pregabalin, but in significantly higher doses. Pregabalin relies heavily on renal clearance for its excretion and the dose should be adjusted in patients with creatine clearance below 60 ml/min. As our patient had a moderate decrease in renal clearance, we prescribed a dose within suggested limits, but in combination with mirtazapine led to the appearance of a drug-induced delirium. In conclusion, combined therapy with low-dose pregabalin and mirtazapine seems to account for the development of delirium in our patient as based on its temporal association with the initiation of this drug combination and its prompt resolution upon withdrawal of these two agents

Disclosure of Interest: None Declared

#### **EPV0824**

## Hyperammonemic encephalopathy in a 46 year old patient treated with valproic acid as treatment for borderline personality disorder: a case report.

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**Introduction:** Valproic acid (VPA) has been used in clinical practice since the 60's, with a relatively favourable safety and efficacy profile. Pancreatitis, hepatotoxicity and teratogenicity are the most significant adverse drug reactions. VPA is also known for causing hyperammonemia, which may be asymptomatic or can present with encephalopathy. VPA-induced hyperammonemic encephalopathy (VHE) is a serious but reversible condition, which requires high clinical suspicion for diagnosis. It may occur acutely or after chronic use of VPA.

**Objectives:** Review how frequent is for valproic acid to cause hyperammonemic encephalopathy, signs to watch out for and how it can be treated.