Objectives: A cohort Temporary Authorization for Use (ATUc) allowed to collect for a 6-month period the first data in real life
Methods: On 02/08/2019 the French National Agency for Medicines and Health Product Safety granted an early access program for Esketamine nasal spray framed by a specific protocol for patients without therapeutic alternatives. Each treatment request was approved based on inclusion and exclusion criteria. Clinical evolution, treatment management and safety were then spontaneously reported by psychiatrists.
Results: From 09/23/2019 to 03/25/2020, 66 patients were treated. The median age was 53 years and 41 (62.1%) were females. At treatment request, 52 patients (79%), presented a severe current depressive episode based on clinical judgment. The median duration of the disease was 12.2 years and the current episode was 2.6 years. Since the beginning of the current depressive episode, all patients (66) were prescribed ≥2 antidepressants (mean 4.2). Esketamine was initiated in a complete hospitalization setting in 27 patients (55.1%) and in day hospitalization in 22 patients (44.9%).Safety profile was consistent with the one described during clinical study. The most frequently adverse events reported (>10%) were dizziness, sedation, sleepiness, anxiety and dissociation. Most of them appeared after treatment administration and were transient.
Conclusions: ATUc ended on 12/18/2019 after Marketing Authorization granted by European Medicines Agency. Data reported by French psychiatrists are the first collected in this specific population and provide descriptive information on patient characteristics, burden of disease; Esketamine management and practical use at hospital level

Disclosure: Data analysis performed by RCTs and poster conception coordinated by Medergy and funded by Janssen
Keywords: treatment resistant depression; spray nasal; glutamatergic pathway; esketamine

EPV0256

Lifetime depression and age-related changes in body composition, cardiovascular measures, grip strength and lung function

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Introduction: Individuals with mental disorders, on average, die prematurely and may experience accelerated biological ageing.
Objectives: We examined sex-specific associations between age and physiological measures in individuals with lifetime depression and healthy controls.
Methods: UK Biobank recruited >500,000 participants, aged 37-73, between 2006–2010. Generalised additive models (GAMs) were used to examine associations between age and multiple cardiovascular, body composition, grip strength and lung function measures. Analyses were conducted separately in males and females with lifetime depression compared to healthy controls.
Results: Analytical samples included up to 342,393 adults (mean age = 55.87 years, SD = 8.09; 52.61% females). We found statistically significant differences between individuals with lifetime depression and healthy controls for most physiological measures, with standardised mean differences between -0.145 and 0.156. There was some evidence that age-related changes in body composition, cardiovascular measures, lung function and heel bone mineral density followed different trajectories in individuals with lifetime depression. However, these differences did not uniformly narrow or widen with age. For example, BMI in females with lifetime depression was approximately 1.1 kg/m^2 higher at age 40 and this difference narrowed to about 0.4 kg/m^2 at age 70. In males, systolic blood pressure was approximately 1 mmHg lower in individuals with lifetime depression at age 45 and this difference widened to about 2.5 mmHg at age 65.
Conclusions: Evidence of differences in ageing trajectories between individuals with lifetime depression and healthy controls was not uniform across physiological measures and differed by sex.

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Keywords: ageing; Depression; public health; physiology

EPV0257

Effects of psilocybin-assisted therapy on treatment-resistant depression

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Introduction: Major depressive disorder is a highly prevalent clinical condition, affecting more than 300 million individuals worldwide. About 1/3 of patients with MDD fail to achieve remission despite treatment with multiple antidepressants and are considered to have treatment-resistant depression (TRD). Novel antidepressants with rapid and sustained effects on mood and cognition could represent a breakthrough in the TRD and may potentially improve or save lives. Psilocybin, a classic hallucinogen, more commonly found in the Psilocybe mushrooms has a combined serotonergic and glutamatergic action. The preliminary evidence of antidepressant effects of psilocybin-assisted therapy indicates the potential of psilocybin-assisted therapy as a novel antidepressant intervention.
Objectives: The authors elaborate a narrative literature review about the effects of Psilocybin-based therapy on patients diagnosed with treatment-resistant depression.
Methods: PubMed database searched using the terms "Treatment-Resistant Depression AND Psilocybin" and targeting clinical trials. References of selected articles and review articles were also assessed.
Results: 2 articles evaluate psilocybin effects in 32 patients with TRD and showed that two doses of psilocybin alongside psychological support significantly reduces depressive symptoms. All patients presented some reduction in symptoms from baseline to one week after the second dose and reproduced immediate and substantial improvements in depression that ultimately could sustain up to 6 months.

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